Integrating the Healthcare Enterprise

IHE Laboratory (LAB) Technical Framework

Volume 2b
LAB TF-2b
Transactions Part B

Revision 6.0 - Final Text

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CONTENTS

1 Introduction

1.1 Overview of IHE

Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration of the information systems that support modern healthcare institutions. Its fundamental objective is to ensure that in the care of patients all required information for medical decisions is both correct and available to healthcare professionals. The IHE initiative is both a process and a forum for encouraging integration efforts. It defines a technical framework for the implementation of established interoperability standards to achieve specific clinical goals. It includes a rigorous testing process for the implementation of this framework, organizes educational sessions, exhibits at major meetings of medical professionals to demonstrate the benefits of this framework and encourage its adoption by industry and users.

The approach employed in the IHE initiative is to support the use of existing standards, e.g., HL7®, ASTM, DICOM, ISO, IETF, OASIS, CLSI and others as appropriate, rather than to define new standards. IHE profiles further constrain configuration choices where necessary in these standards to ensure that they can be used in their respective domains in an integrated manner between different actors. When clarifications or extensions to existing standards are necessary, IHE refers recommendations to the relevant standards bodies.

1.2 Overview of the Laboratory Technical Framework

1.2.1 Production

This document, the Laboratory Technical Framework (LAB TF), defines specific implementations of established standards to achieve integration goals of clinical laboratories with other components of a healthcare enterprise or with a broader community of healthcare providers, hereafter called a healthcare community.

This document is updated annually, following a period of public review, and maintained regularly through the identification and correction of errata. The current version, rev. 6.0 Final Text, specifies the IHE transactions defined and implemented as of July2015. The latest version of the document is always available via the Internet at http://www.ihe.net/Technical_Frameworks.

It has been produced with the help of the following organizations:

- CAP (College of American Pathologists)
- ASIP Santé (Agence des Systèmes d'Information Partagés de Santé) formerly GMSIH (Groupement pour la Modernisation du Système d'Information Hospitalier)
- JAHIS (Japanese Association of Healthcare Information Systems Industry)
- IHE-J (IHE Japan)
- SFIL (Société Française d'Informatique de Laboratoire)
- HL7® and its affiliate organizations

- RSNA (Radiological Society of North America)

1.2.2 How the Laboratory Technical Framework is organized

The IHE Laboratory Technical Framework identifies a subset of the functional components of the healthcare enterprise or healthcare community, called IHE actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth, and is organized in volumes:

- **Volume 1** of the Laboratory Technical Framework (LAB TF-1) provides a high-level view of IHE functionality, showing the transactions organized into functional units called integration profiles that highlight their capacity to address specific integration requirements for clinical purposes.
- **Volumes 2a, 2b, and 2x** of the Laboratory Technical Framework (LAB TF-2a, Lab TF-2b, LAB TF-2x) provide a detailed technical description of each message-based transaction and of its messages.
- **Volume 3** of the Laboratory Technical Framework (LAB TF-3) provides a detailed technical description of each document-based transaction, its persistent content and binding.
- **Volume 4** of the Laboratory Technical Framework (LAB TF-4) has been deprecated

1.3 Audience

The intended audience of this document is:

- Technical staff of vendors participating in the IHE initiative
- IT managers of healthcare institutions and healthcare communities
- Experts involved in standards development
- Anyone interested in the technical aspects of integrating healthcare information systems

1.4 Relationship to Standards

The IHE Laboratory Technical Framework identifies functional components of a distributed healthcare environment (referred to as IHE actors), solely from the point of view of their interactions in the healthcare enterprise. At its current level of development, it defines a coordinated set of transactions based on HL7®, IETF, ISO, CLSI, OASIS and W3C standards. As the scope of the IHE initiative expands, transactions based on other international standards may be included as required.

In some cases, IHE recommends selection of specific options supported by these standards; however, IHE does not introduce technical choices that contradict conformance to these standards. If errors in or extensions to existing standards are identified, IHE's policy is to report them to the appropriate standards bodies for resolution within their conformance and standards evolution strategy.

IHE is therefore an implementation framework, not a standard. Conformance claims for products must still be made in direct reference to specific standards. In addition, vendors who have

implemented IHE integration capabilities in their products may publish IHE Integration Statements to communicate their products' capabilities. Vendors publishing IHE Integration Statements accept full responsibility for their content. By comparing the IHE Integration Statements from different products, a user familiar with the IHE concepts of actors and integration profiles can determine the level of integration between them.

1.5 Relationship to Real-world architectures

The IHE actors and transactions are abstractions of the real-world healthcare information system environment. While some of the transactions are traditionally performed by specific product categories (e.g., Hospital Information System, Electronic Patient Record, Clinical Information System, Laboratory Information System, Laboratory Automation System, analyzer, robotic transportation system and other pre and post-analytic process equipment), the IHE Laboratory Technical Framework intentionally avoids associating functions or actors with such product categories. For each actor, the IHE Laboratory Technical Framework defines only those functions associated with integrating information systems. The IHE definition of an actor should therefore not be taken as the complete definition of any product that might implement it, nor should the framework itself be taken to comprehensively describe the architecture of a healthcare information system.

1.6 History of Annual Changes

The IHE Technical Framework is updated annually to reflect new profiles, corrections and new transactions.

1.6.1 Scope of Changes Introduced in the Current Year (2015)

This revision 6.0 incorporates the following changes:

A minor correction from Change Proposal #293, by removing duplication of content that was present in both this chapter and chapter 2a, where it can be found now.

Clarification of use of the SAC segment in LAB-61 (see Section 3.33.6) and LAB-62 (see Section 3.34.7

1.6.2 Scope of Changes Introduced in Year 2013

This revision 5.0 of Vol 2b is unchanged. It will be the basis for 2014 Connectathons.

1.6.3 Scope of Changes Introduced in Year 2012

This revision 4.0 incorporates a number of Change Proposals resulting from the Connectathons of years 2011 – 2012. It will be the basis for 2013 Connectathons.

1.6.4 Scope of Changes Introduced in Year 2011

This revision 3.0 incorporates a number of Change Proposals resulting from the Connectathons of years 2008 – 2010. It will be the basis for Connectathons 2011 (in Europe, Japan and other regions) and 2012 (in North-America).

The major enhancements are:

- Batch option and various refinements added to transaction LAB-51 (LCSD Profile)
- Fixes and refinements on some field definitions in various transactions.

1.6.5 Scope of Changes Introduced in Year 2008

The main changes introduced by revision 2.1 were the following:

- Refined descriptions of segments ORC, SAC, TQ1, OBX, SPM (see sections 3.5 to 3.9)
- Microbiology reporting rules (see section 3.11 and example in section 19.5)
- Option "Report Facsimile For Order Group" (see sections 4, 6 and example in section 19.4)
- HL7® Ack, and MSA, ERR segments descriptions externalized to ITI TF-2:Appendix C
- Support of HL7® v2.5.1 (see OBX segment description in section 3.9)
- Cleanup of all examples messages in section 19

1.7 Comments

IHE International welcomes comments on this document and the IHE initiative. They should be directed to the co-chairs of the IHE Laboratory Committee, using the address lab@ihe.net.

1.8 Copyright Permissions

1.9 IHE Technical Framework Development and Maintenance Process

The IHE Laboratory Technical Framework is being continuously extended and maintained by the IHE Laboratory Technical committee. The development and maintenance process of the Framework follows a number of principles to ensure stability of the specification so that both vendors and users may use it reliably in specifying, developing and acquiring systems with IHE integration capabilities.

The first of these principles is that any extensions, clarifications and corrections to the Technical Framework must maintain backward compatibility with previous versions of the framework in order to maintain interoperability with systems that have implemented IHE actors and Integration Profiles defined there.

1.10 Glossary

See Glossary section in Volume 1: LAB TF-1:1.11

2 Conventions

The content of this chapter is in Volume 2a. See LAB TF-2a:2

3 IHE Transactions

3.30 Initiate POCT on a patient specimen (LAB-30)

This transaction is used on a persistently connected POCRG. It implements option *Patient Identity Checking* of the LPOCT Integration Profile.

3.30.1 Scope

The point of care devices often work with a patient (or visit) identifier scanned or typed on their user interface. The purpose of this transaction is to provide a real-time control of this patient/visit identifier, and to avoid any risks of mistyping.

This transaction is used by a POCRG in a ward to inform the POCDM that a new point of care set of tests is about to start on a patient specimen. The POCRG delivers the relevant information related to the testing, including a patient/visit identifier. The POCDM checks the information received, and particularly verifies that the patient/visit identifier is associated with this ward. It then sends back an acknowledgement carrying either the patient's name or a textual error (e.g., "Patient unknown"). The POCRG displays the information received in the acknowledgement, enabling the operator to check that he is testing on the right patient.

3.30.2 Use Case Roles

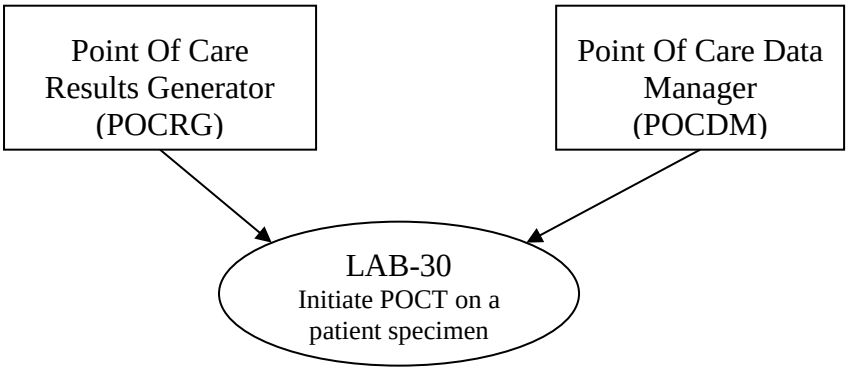


Figure 3.30.2-1: Use case for LAB-30

Actor: POCRG

Role: Informs the POCDM that a new set of tests is starting, giving all relevant information related to this point of care testing. Waits for the patient identity in the acknowledgement, and displays this identity on its user interface.

Actor: POCDM

Role: Checks the information received related to the point of care testing, searches for the patient data related to the patient identifier received, and sends an acknowledgement back to the POCRG. The acknowledgement carries either the patient's name, or an error (e.g., "Test unauthorized on this device")

3.30.3 Referenced Standard

POCT1-A: Device Message Layer (DML) defined in Appendix B of POCT1-A standard.

In the POCT1-A standard, the POCRG actor of IHE is called the ***Device*** and the POCDM actor of IHE is called the ***Observation Reviewer***.

This transaction LAB-30 uses the ***Continuous Mode*** defined in section 4.2 of Appendix B of POCT1-A. This continuous mode is usable if the POCRG has a persistent link with the POCDM, which is the prerequisite for using transaction LAB-30.

3.30.4 Interaction Diagram

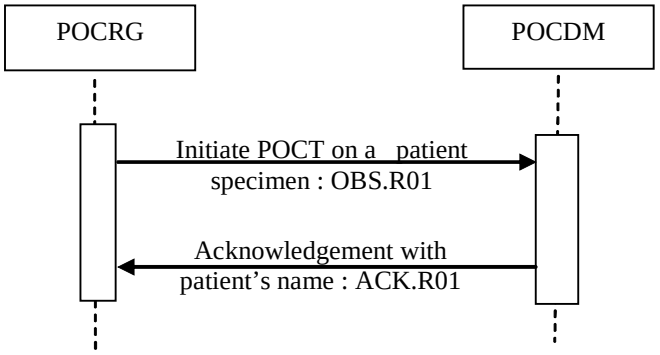


Figure 3.30.4-1: Interaction Diagram [LAB-30]

3.30.4.1 Patient Identity Checking

The POCT1-A standard currently does not describe this interaction for real-time patient identity checking. Transaction LAB-30 of this IHE profile will use as initial message a "patient-related observation message" OBS.R01 as defined in POCT1-A Appendix B. The status of the Service object will be valued to "INI" (as "initiate a point of care testing"), and no results will be provided in the message. This value "INI" is added by IHE to the table of service status defined in POCT1-A.

The Acknowledgement message ACK.R01 from the POCDM to the POCRG, will carry the patient's name as a note related to the acknowledgement, within the note_txt field of the Acknowledgement object.

The two messages are exchanged within an "***Observations***" ***Topic*** within the ***Continuous Mode*** of POCT1-A Device Messaging Level.

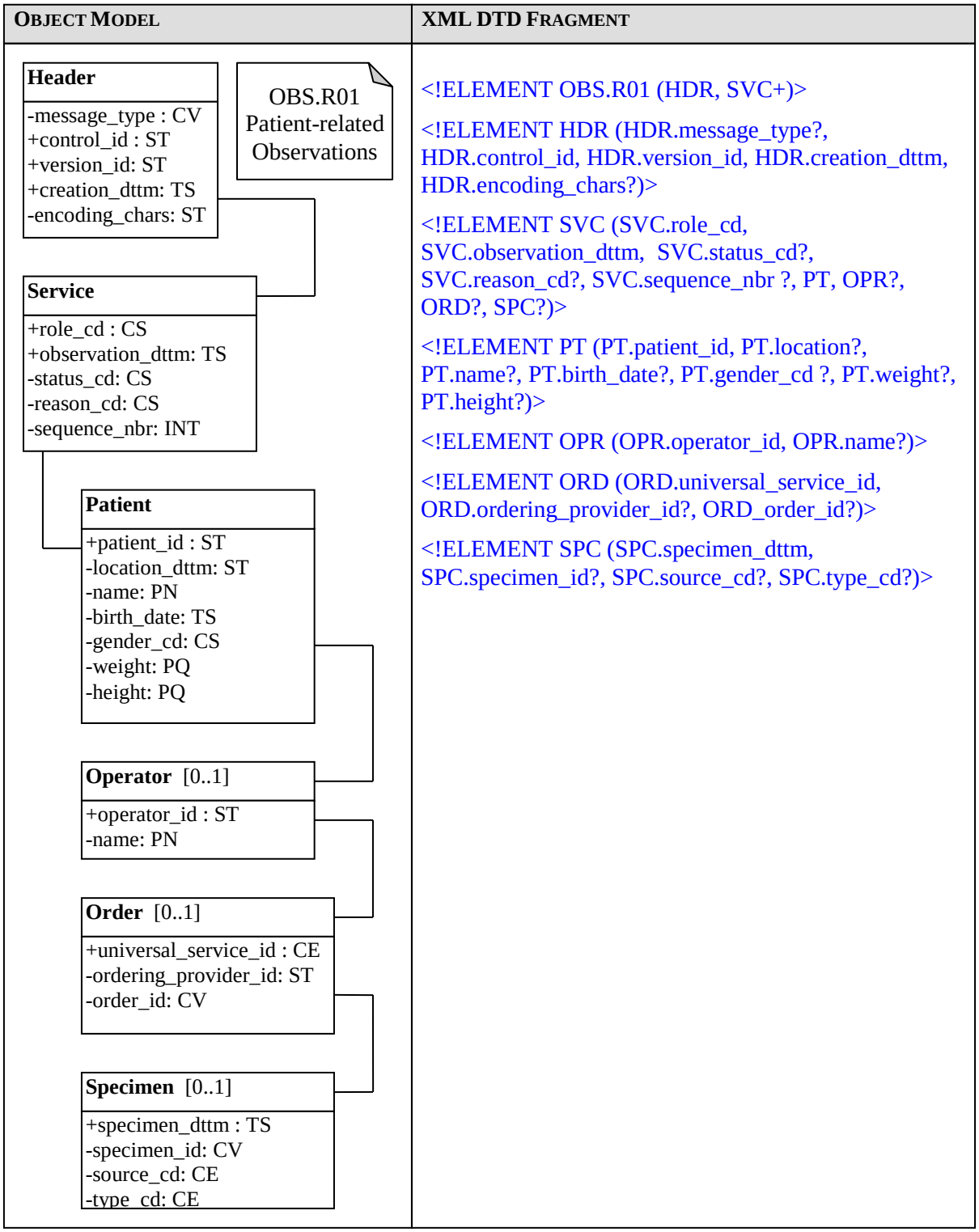
3.30.5 Trigger Events

An operator (caregiver or patient) sets a patient specimen on the point of care device (the POCRG Actor supporting the option "Patient identity checking"), and enters relevant information including the operator's ID and the patient's ID. This triggers the initial message of Transaction LAB30: "Initiate POCT on a patient specimen".

3.30.6 Message Semantics

3.30.6.1 Initiate POCT on a patient specimen – Message OBS.R01, status_cd = 'INI'

The figure below describes the use of message OBS.R01 in Transaction LAB-30. It respects the formalism of POCT1-A, Annex B.



330

Figure 3.30.6.1-1: Message OBS.R01 in Transaction LAB-30

3.30.6.1.1 Use of the Service Object

One and only one occurrence of this object must appear in the context of Transaction LAB-30.

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
role_cd	CS	R	[1..1]	Value “OBS”: Patient test observation
observation_dttm	TS	R	[1..1]	Starting date/time of the test
status_cd	ST	R	[1..1]	Value “INI”: The point of care test is about to start. No observation produced yet.
reason_cd	ST	X	[0..0]	This code is not used in the context of LAB-30.
sequence_nbr	ST	X	[0..0]	This number is not used in the context of LAB-30.

335

Table 48 of POCT1-A: Service Status code Field Values

Code	Meaning	Description
NRM	Normal	This test was performed under normal conditions
OVR	Override	This test was performed in an ‘override’ or ‘stat’ circumstance. Some normal procedures (e.g., QC) may not have been followed.
UNK	Unknown	It is not known under what circumstances this test was performed.
INI	Test starting	This test is going to start for this patient. Value added by IHE to this table

The last value “INI” is added by this LPOCT IHE profile, for the unique purpose of this Transaction LAB-30.

340

3.30.6.1.2 Use of the Patient Object

One and only one occurrence of this object must appear in the context of Transaction LAB-30.

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
patient_id	ST	R	[1..1]	A unique identifier for the patient, supposed to be known from the POCDM Actor
location	ST	RE	[0..1]	Location of the patient
name	PN	X	[0..0]	Patient name. Not used in the context of LAB-30.
birth_date	TS	X	[0..0]	Patient date of birth. Not used in the context of LAB-30.
gender_cd	CS	X	[0..0]	Patient gender. Not used in the context of LAB-30.
weight	PQ	X	[0..0]	Patient weight. Not used in the context of LAB-30.
height	PQ	X	[0..0]	Patient height. Not used in the context of LAB-30.

3.30.6.1.3 Use of the Operator Object

345 One and only one occurrence of this object must appear in the context of Transaction LAB-30.

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
operator_id	ST	R	[1..1]	A unique identifier for the operator

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
name	PN	RE	[0..1]	Operator's name. Required if available on the POCRG.

3.30.6.1.4 Use of the Order Object

Zero or one occurrence of this object may appear in the context of Transaction LAB-30.

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
universal_service_id	CE	R	[1..1]	Identifies the service provided by these observations. LOINC is the preferred encoding scheme. The CE data type allows transmission of two encodings, if appropriate.
ordering_provider_id	ST	RE	[0..1]	An identifier that uniquely identifies the provider who ordered this service.
order_id	CV	O	[0..1]	An identifier that uniquely identifies this service instance. This field may contain an order id, accession number, or other such identifier.

3.30.6.1.5 Use of the Specimen object

Zero or one occurrence of this object may appear in the context of Transaction LAB-30.

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
specimen_dttm	TS	R	[1..1]	Time the specimen was drawn.
specimen_id	CV	O	[0..1]	Code identifying the specimen
source_cd	CE	O	[0..1]	Location of the specimen. Coded in table 51 of POCT1-A
type_cd	CE	O	[0..1]	Type of the specimen. Coded in table 52 of POCT1-A

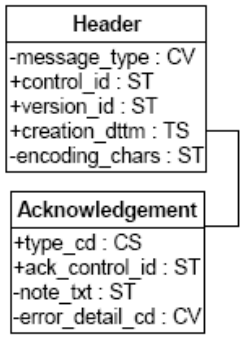
3.30.6.1.6 Example Message OBS.R01: Initiate POCT on a Patient Specimen

```
<OBS.R01>
        <HDR>
                <HDR.control_id V=“12345”/>
                <HDR.version_id V=“POCT1”/>
                <HDR.creation_dttm V=“2005-05-16T16:30:00+01:00”/>
        </HDR>
        <SVC>
                <SVC.role_cd V=“OBS”/>
                <SVC.observation_dttm V=“2005-05-16T16:30:00+01:00”/>
                <SVC.status_cd V=“INI”/>
                <PT>
                        <PT.patient_id V=“888888”/>
                </PT>
                <OPR>
                        <OPR.operator_id V=“Nurse007”/>
                        <OPR.name V=“Nancy Nursery”>
                                < GIV V=“Nancy”/>
                                < FAM V=“Nursery”/>
                        </OPR.name>
                </OPR>
                <ORD>
                        <ORD.universal_service_id V="BG-OXI-ELECT"/>
                        <ORD.ordering_provider_id V="Facility1"/>
                </ORD>
        </SVC>
</OBS.R01>
```

355 In this example, the operator Nancy Nursery wants to start a blood gas test on a patient specimen for a patient whose enterprise id is « 888888 ». The device is in a hospital in Palermo one hour ahead GMT.

3.30.6.2 Acknowledgement with Patient Name – Message ACK.R01

The figure below is extracted from POCT1-A, Annex B.

Object Model	XML DTD Fragment
	<!ELEMENT ACK.R01 (HDR, ACK)> <!ELEMENT HDR (HDR.message_type?, HDR.control_id, HDR.version_id, HDR.creation_dttm, HDR.encoding_chars?)> <!ELEMENT ACK (ACK.type_cd, ACK.ack_control_id, ACK.note_txt?, ACK.error_detail_cd?)>

360

3.30.6.2.1 Use of the Header Object

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
message_type	CV	X	[0..0]	Not used: Redundant with the root element of the message
control_id	ST	R	[1..1]	unique identifier of the instance of this acknowledgement message
version_id	ST	R	[1..1]	"POCT1"
creation_dttm	TS	C	[0..1]	date/time of creation of this acknowledgement

3.30.6.2.2 Use of the Acknowledgement Object

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
type_cd	CS	R	[1..1]	AA: Application Accept AE: Application Error
ack_control_id	ST	R	[1..1]	The unique identifier of the acknowledged message
note_txt	ST	R	[1..1]	This field is required in the context of IHE Transaction LAB-30. It contains either the patient's name in case of Application Accept or a text describing the error condition in case of Application Error.
error_detail_cd	CV	R	[1..1]	A code detailing the error. Described in Table 14 of Annex B of POCT1-A.

365

Condition predicate for the field **note_txt**:

If the POCDM has matched an existing patient, and has controlled that the information received within the OBS.R01 message is consistent with this patient and that the test for this patient on this device by this operator is authorized, then the POCDM sends back a positive
370 acknowledgement (type_cd = "AA", error_detail_cd = "0"). In this case, the note_txt is required and shall be valued with the patient's name, using any display oriented string format.

Example of positive acknowledgement for patient Jeanne DUPONT:

```
<ACK.R01>
        <HDR>
                < HDR.control_id V=“45678”/>
                < HDR.version_id V=“POCT1”/>
                < HDR.creation_dttm V=“2005-05-16T16:30:00”/>
        </HDR>
        <ACK>
                < ACK.type_cd V=“AA”/>
                < ACK.ack_control_id V=“12345”/>
                < ACK.note_txt V=“ DUPONT Jeanne ”/>
                < ACK.error_detail_cd V= “0”/>
        </ACK>
</ACK.R01>
```

If the POCDM has failed to match a patient from the patient identifier received within the OBS.R01 message, then it sends back a negative acknowledgement (type_cd = “AA”, error_detail_cd = “202”), with the field note_txt containing a text explaining the error condition.

Example of negative acknowledgement:

```
<ACK.R01>
        <HDR>
                < HDR.control_id V=“45679”/>
                < HDR.version_id V=“POCT1”/>
                < HDR.creation_dttm V=“2005-05-16T16:30:00”/>
        </HDR>
        <ACK>
                < ACK.type_cd V=“AE”/>
                < ACK.ack_control_id V=“12345”/>
                < ACK.note_txt V=“ Unknown patient identifier 888888”/>
                < ACK.error_detail_cd V= “202”/>
        </ACK>
</ACK.R01>
```

3.30.7 Expected Actions

When receiving the message “Initiate POCT on a patient specimen”, the POCDM must search for the patient using the patient ID, and must check the information related to the testing. Then the POCDM builds its Acknowledgement message and sends it to the POCRG.

When receiving the message “Acknowledgement with patient identity”, the POCRG must display as much of the patient identity as possible, to allow the operator to verify this identity.

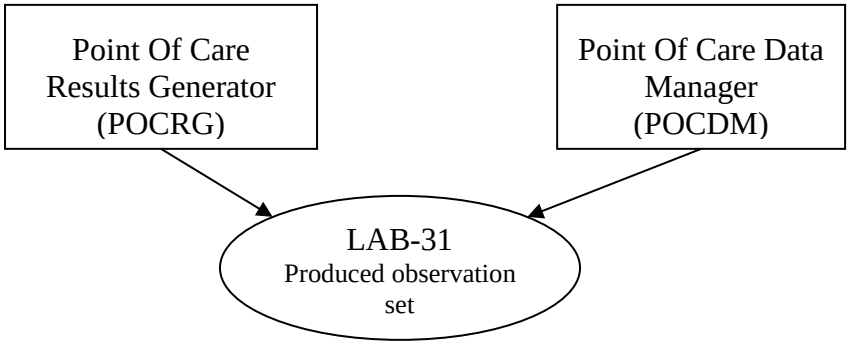
3.31 Produced Observation Set (LAB-31)

3.31.1 Scope

The POCRG sends a set of observations to the POCDM. The POCDM checks the content of this set of results. If it is acceptable, the POCDM stores it and acknowledges it to the POCRG; otherwise the POCDM rejects the set of results and sends a negative acknowledgement back to the POCRG that will display it to its user.

The set of observations may be obtained on a patient specimen or on a QC specimen.

3.31.2 Use Case Roles



Actor: POCRG

Role: Sends to the POCDM a new set of observations obtained on a patient specimen or a QC specimen. Waits for the acknowledgement of this set of observations

Actor: POCDM

Role: Checks the information received with this set of observations, controls the results against its own business rules, accepts them or rejects them, stores the accepted results, and acknowledges them to the POCRG.

3.31.3 Referenced Standard

POCT1-A: Device Message Layer (DML) defined in Appendix B.

This LPOCT Profile describes the upper-layer messaging protocol (DML) of POCT1-A. The POCRG Actor of IHE is called the "***Device***" in POCT1-A. The POCDM Actor of IHE is called "***Observation Reviewer***" in POCT1-A.

This transaction LAB-31 can be used on the ***Basic Profile*** defined in section 4.1 of Appendix B of POCT1-A, or on the ***Continuous Mode*** defined in section 4.2 of the same document.

3.31.4 Interaction Diagram

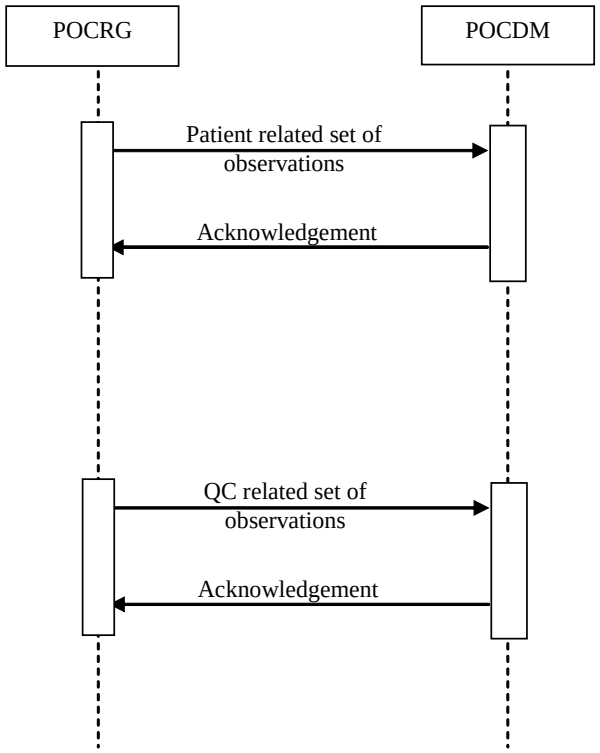


Figure 3.31.4-1: Interaction Diagram for [LAB-31]

The message "Patient related set of observations" of the diagram above uses the Observations message **OBS.R01** defined in Appendix B – section 6.10 of POCT1-A.

The message "QC related set of observations" uses the Observations message **OBS.R02** defined in the same section of POCT1-A.

3.31.5 Trigger Events

1. The "Patient related set of observations" message is triggered by any new patient observations obtained on the POCRG Actor.
2. The "QC related set of observations" message is triggered by any new non-patient observations (internal or external QC, calibration) obtained on the POCRG Actor.

When using the "***Continuous Mode***" of POCT1-A the above events trigger the Observations messages at once.

When using the "***Basic Profile***" of POCT1-A the sending of these Observation messages requires these prior conditions:

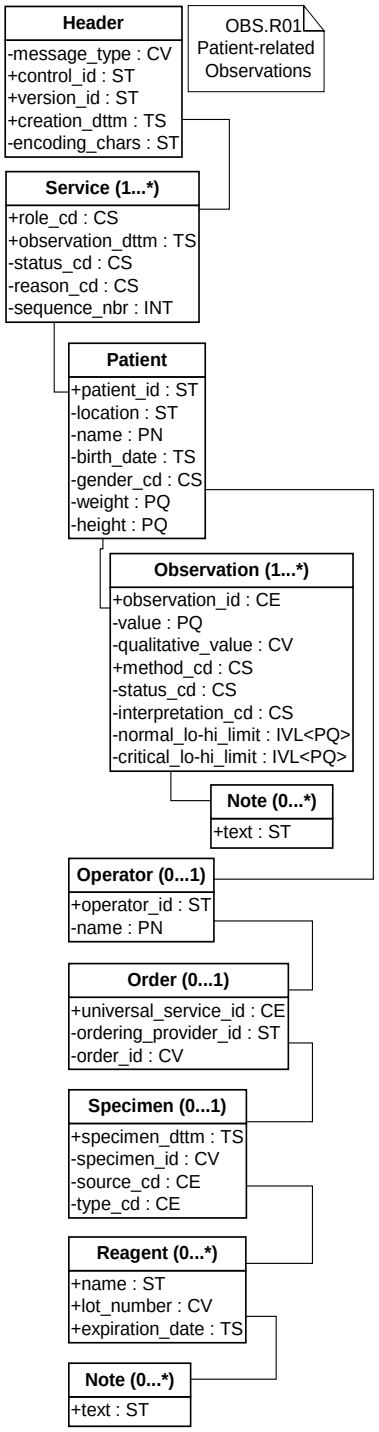
1. Establishment of a ***Conversation*** between POCRG and POCDM. (***Topic Hello***)
2. The sending of the message "Device status" by the POCRG Actor and its acknowledgement by the POCDM Actor. (***Topic Device Status***)
3. The sending of the message "Request Observations" by the POCDM to the POCRG (if the Conversation is not in continuous mode).

3.31.6 Message Semantics

3.31.6.1 Message OBS.R01: Patient-Related Set of Observations

The figure below is extracted from POCT1-A, Annex B.

OBJECT MODEL	XML DTD FRAGMENT




```
<!ELEMENT OBS.R01 (HDR, SVC+)>

<!ELEMENT HDR (HDR.message_type?, HDR.control_id,
    HDR.version_id, HDR.creation_dttm, HDR.encoding_chars?)>

<!ELEMENT SVC (SVC.role_cd, SVC.observation_dttm, SVC.status_cd?,
    SVC.reason_cd?, SVC.sequence_nbr?, PT, OPR?, ORD?, SPC?,
    RGT*, NTE*)>

<!ELEMENT PT (PT.patient_id, PT.location?, PT.name?, PT.birth_date?,
    PT.gender_cd?, PT.weight?, PT.height?, OBS+)>

<!ELEMENT OBS (OBS.observation_id, OBS.value?,
    OBS.qualitative_value?, OBS.method_cd, OBS.status_cd?,
    OBS.interpretation_cd?, OBS.normal_lo-hi_limit?,
    OBS.critical_lo-hi_limit?, NTE*)>

<!ELEMENT OPR (OPR.operator_id, OPR.name?)>

<!ELEMENT ORD (ORD.universal_service_id,
    ORD.ordering_provider_id?, ORD.order_id?)>

<!ELEMENT SPC (SPC.specimen_id?, SPC.specimen_dttm,
    SPC.source_cd?, SPC.type_cd?)>

<!ELEMENT RGT (RGT.name, RGT.lot_number, RGT.expiration_date)>

<!ELEMENT NTE (NTE.text)>
```

Figure 3.31.6.1-1: Patient-Related Observation Message Model, POCT1-A – Appendix B

3.31.6.1.1 Use of the Service Object

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
role_cd	CS	R	[1..1]	Value "**OBS**": Patient test observation
observation_dttm	TS	R	[1..1]	production date/time of this set of observations
status_cd	ST	R	[1..1]	One of the values listed in table 48 of POCT1-A, Annex B
reason_cd	ST	R	[1..1]	One of the values listed in table 49 of POCT1-A, Annex B
sequence_nbr	ST	O	[O..1]	An optional number to indicate the position of this service in a historical list of services performed by this Device. This number is unique only across a single Device, and may wrap (e.g., a 'use counter').

Table 48 of POCT1-A: Service Status code Field Values

Code	Meaning	Description
NRM	Normal	This test was performed under normal conditions
OVR	Override	This test was performed in an 'override' or 'stat' circumstance. Some normal procedures (e.g., QC) may not have been followed.
UNK	Unknown	It is not known under what circumstances this test was performed.

445

Table 49 of POCT1-A: Service Reason Code Field Values

Code	Meaning	Description
NEW	New	Default. This is a new set of observations.
RES	Resent	This set of observations is being resent.
EDT	Edited	Some fields of this set of observations have been edited since last transmission

3.31.6.1.2 Use of the Patient Object

One and only one occurrence of Patient per Service:

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
patient_id	ST	R	[1..1]	A unique identifier for the patient, supposed to be known from the POCDM Actor
location	ST	RE	[0..1]	Location of the patient. Required if known.
name	PN	RE	[0..1]	Patient name. Required if known.
birth_date	TS	RE	[0..1]	Patient date of birth. Required if known.
gender_cd	CS	RE	[0..1]	Patient gender. Required if known.
weight	PQ	C	[0..1]	Patient weight. Required if known and relevant for the test.
height	PQ	C	[0..1]	Patient height. Required if known and relevant for the test.

3.31.6.1.3 Use of the Observation Object

One or more occurrences of Observation per Patient:

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
observation_id	CE	R	[1..1]	The test identifier, preferably coded with LOINC
value	PQ	C	[0..1]	The observation result, if expressed quantitatively (i.e., a numerical value with units).
qualitative_value	CV	C	[0..1]	The observation result, if expressed qualitatively. POCT1-A, Annex B provides a list of codes in table 35. This list is extensible.
method_cd	CS	R	[1..1]	Origin of the result. Coded in table 36 of POCT1-A, Annex B. This LPOCT Profile authorizes only these values: **C** = Calculated (The value was calculated) **D** = Default (The value is a default value) **E** = Estimated **I** = Input (The value was externally input to the POCRG) **M** = Measured (The value was measured on the POCRG)
status_cd	CS	R	[1..1]	Status of the result. Coded in table 37 of POCT1-A, Annex B. This IHE LPOCT Profile authorizes only this value for patient-related results: A = Accepted
interpretation_cd	CS	C	[0..1]	Interpretation of the result (abnormal flags). Coded in table 38 of POCT1-A, Annex B: **L** = below low normal **H** = above high normal **LL** = below lower panic limits **HH** = above upper panic limits **<** = below absolute low-off instrument scale **>** = above absolute high-off instrument scale **N** = normal **A** = abnormal (applies to nonnumeric results) **AA** = very abnormal (applies to nonnumeric results) **null** = no range defined or normal ranges don't apply **U** = significant change up **D** = significant change down **B** = better (use when direction not relevant) **W** = worse (use when direction not relevant)
normal_lo-hi_limit	IVL<PQ>	R	[1..1]	The low and high limit range for a normal result
critical_lo-hi_limit	IVL<PQ>	R	[1..1]	The low and high limit range outside which clinical review is required

Condition predicate for fields ***value***, ***qualitative_value*** and ***interpretation_cd***:

Every Observation object instance must contain either a value or a qualitative_value field. The interpretation_cd field may be used to provide additional information about the quantitative or qualitative value.

3.31.6.1.4 Use of the Note Object Related to the Observation Object

Zero or one occurrence of this object may appear below an observation. The note is a comment related to the observation.

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
text	ST	R	[1..1]	Comment of the observation

460

3.31.6.1.5 Use of the Operator Object

One and only one occurrence.

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
operator_id	ST	R	[1..1]	A unique identifier for the operator
name	PN	RE	[0..1]	Operator's name. Required if available on the POCRG.

3.31.6.1.6 Use of the Order Object

465 One and only one occurrence.

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
universal_service_id	CE	R	[1..1]	Identifies the service provided by these observations. LOINC is the preferred encoding scheme. The CE data type allows transmission of two encodings, if appropriate.
ordering_provider_id	ST	RE	[0..1]	An identifier that uniquely identifies the provider who ordered this service.
order_id	CV	O	[0..1]	An identifier that uniquely identifies this service instance. This field may contain an order id, accession number, or other such identifier.

3.31.6.1.7 Use of the Specimen Object

Zero or one occurrence.

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
specimen_dttm	TS	R	[1..1]	Time the specimen was drawn.
specimen_id	CV	O	[0..1]	Code identifying the specimen
source_cd	CE	O	[0..1]	Location of the specimen. Coded in table 51 of POCT1-A, Annex B
type_cd	CE	R	[1..1]	Type of the specimen. Coded in table 52 of POCT1-A, Annex B

3.31.6.1.8 Use of the Reagent Object

Zero or one occurrence.

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
name	ST	RE	[0..1]	The manufacturer's name for the reagent
lot_number	CV	R	[1..1]	The lot number of reagent used
expiration_date	TS	RE	[0..1]	The date past which the reagent should not be used

3.31.6.1.9 Use of the Note Object

Zero or more occurrences of this object may appear below the Service object. The note is a comment related to the service (i.e., the set of observations).

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
text	ST	R	[1..1]	Comment of the observation

3.31.6.1.10 Example Message of Patient Observations


```
<OBS.R01>
        <HDR>
                <HDR.control_id V=“12345”/>
                <HDR.version_id V=“POCT1”/>
                <HDR.creation_dttm V=“2005-05-16T16:30:00+1:00”/>
        </HDR>
        <SVC>
                <SVC.role_cd V=“OBS”/>
                <SVC.observation_dttm V=“2005-05-16T16:30:00+1:00”/>
                <SVC.status_cd V=“NRM”/>
                <SVC.reason_cd V=“NEW”/>
                <PT>
                        <PT.patient_id V=“888888”/>
                        <PT.location V=“ICU-Bed3”/>
                        <PT.name V=“Pat Patient”>
                                <GIV V=“Patrick”>
                                <FAM V=“Patient”>
                        </ PT.name >
                        <PT.birth_date V=“1958-10-31”/>
                        <PT.gender_cd V=“M”/>
                        <OBS>
                                < OBS.observation_id V=“2703-7” SN=“LN” DN=“Oxygen”/>
                                <OBS.value V="110" U="mmHg"/>
                                 <OBS.method_cd V="M"/>
                                <OBS.status_cd V="A"/>
                                <OBS.interpretation_cd V="H"/>
                                <OBS.normal_lo-hi_limit V="[83;108]" V="mmHg"/>
                                <OBS.critical_lo-hi_limit V="[40;130]" V="mmHg"/>
                        </OBS>
                        <OBS>
                                < OBS.observation_id V=“11557-6” SN=“LN” DN=“Carbon Dioxyd”/>
                                <OBS.value V="33.2" U="mmHg"/>
                                 <OBS.method_cd V="M"/>
                                <OBS.status_cd V="A"/>
                                <OBS.interpretation_cd V="L"/>
                                <OBS.normal_lo-hi_limit V="[35.0;48.0]" V="mmHg"/>
                                <OBS.critical_lo-hi_limit V="[20.0;60.0]" V="mmHg"/>
                        </OBS>
                        <NTE>
                                <NTE.text V=“result below reference ranges, within critical ranges”/>
                        </NTE>
                        <OBS>
                                < OBS.observation_id V=“11558-4” SN=“LN” DN=“pH”/>
                                <OBS.value V="7.47"/>
                                 <OBS.method_cd V="M"/>
                                <OBS.status_cd V="A"/>
                                <OBS.interpretation_cd V="H"/>
                                <OBS.normal_lo-hi_limit V="[7.35;7.45]" V="mmHg"/>
                                <OBS.critical_lo-hi_limit V="[7.00;7.60]" V="mmHg"/>
                        </OBS>
                </PT>
                <OPR>
                        <OPR.operator_id V=“Nurse007”/>
                        <OPR.name V=“Nancy Nursery”>
                                < GIV V=“Nancy”/>
                                < FAM V=“Nursery”/>
                        </OPR.name>
                </OPR>
                <ORD>
                        <ORD.universal_service_id V="BG-OXI-ELECT"/>
                        <ORD.ordering_provider_id V="Facility1"/>
                </ORD>
                <SPC>
                        <SPC.specimen_dttm V="2005-05-19T10:20:00-1.00"/>
                        <SPC.source_cd V="LLFA"/>
                        <SPC.type_cd V="BLDA"/>
                </SPC>
                <NTE>
                        <NTE.text V=“Battery approved by Dr Esclapios”/>
                </NTE>
        </SVC>
</OBS.R01>
```


3.31.6.1.11 Message OBS.R02: QC Related Set of Observations

The figure below is extracted from POCT1-A, Annex B.

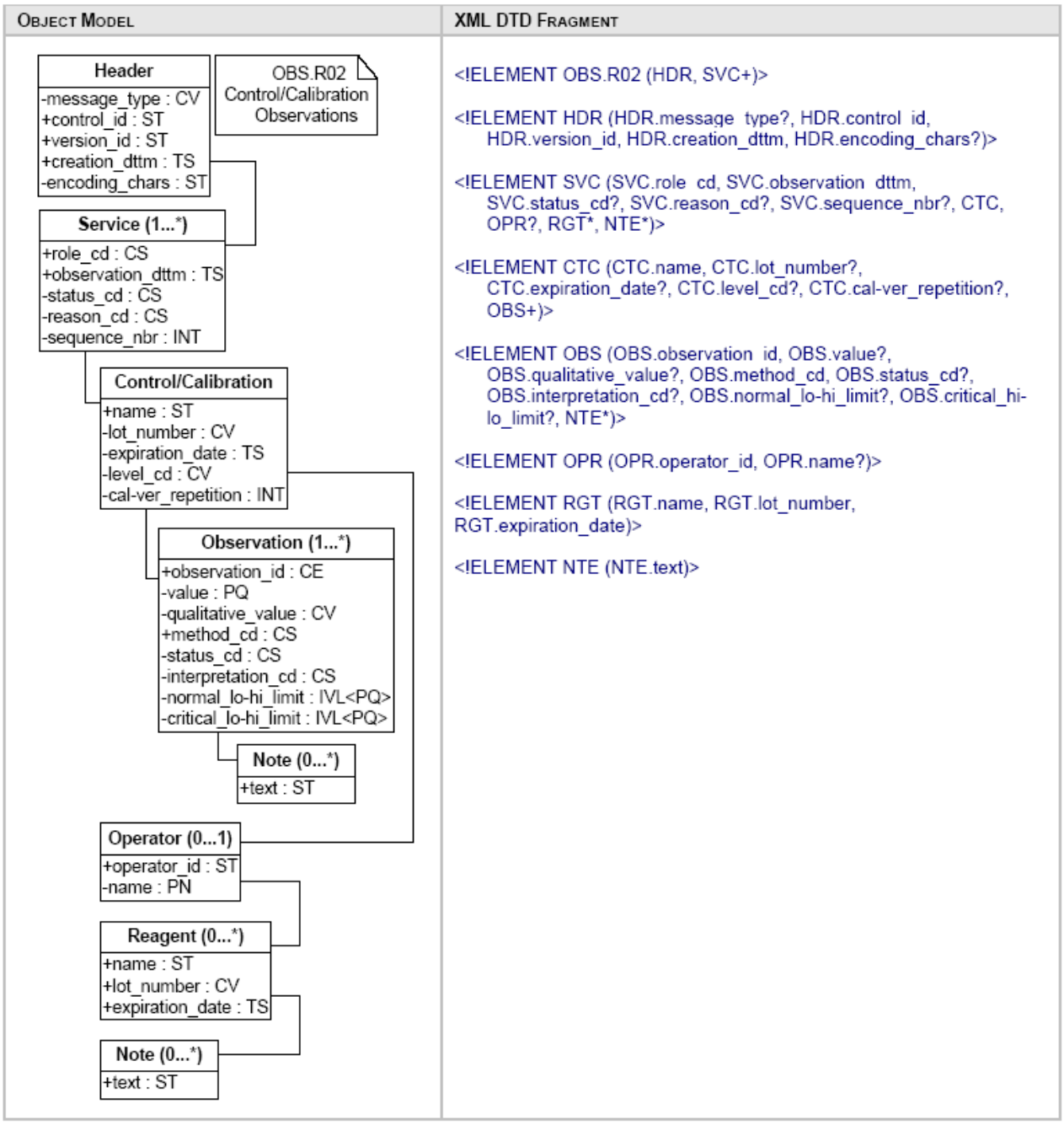


Figure 45. Nonpatient-related Observation Message Model

480

3.31.6.1.12 Use of the Service Object

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
role_cd	CS	R	[1..1]	The following values are authorized within OBS.R02 message, taken from table 47 in POCT1-A, Annex B: **LQC** = Liquid QC (observation from a liquid QC test) **EQC** = Electronic QC (observation from an electronic QC test) **CVR** = Calibration verification **CAL** = Calibration **PRF** = Proficiency test
observation_dttm	TS	R	[1..1]	production date/time of this set of observations
status_cd	ST	R	[1..1]	One of the values listed in table 48 of POCT1-A, Annex B (see section Y.6.1.1 in this document)
reason_cd	ST	R	[1..1]	One of the values listed in table 49 of POCT1-A, Annex B (see section Y.6.1.1 in this document)
sequence_nbr	ST	O	[O..1]	An optional number to indicate the position of this service in a historical list of services performed by this Device. This number is unique only across a single Device, and may wrap (e.g., a 'use counter').

3.31.6.1.13 Use of the Control/Calibration Object

485 One and only one occurrence of Control/Calibration per Service:

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
name	ST	RE	[0..1]	The manufacturer's name for the QC/Calibration material
lot_number	CV	R	[1..1]	The vendor-specific lot number of the QC/Calibration material
expiration_date	TS	RE	[0..1]	The date past which the reagent should not be used
level_cd	CV	C	[0..1]	The level for the QC test or for the calibration verification test. Not applicable to proficiency tests nor to calibration tests.
cal-ver_repetition	INT	C	[0..1]	Only applicable to calibration verification: If tests within a linearity sequence are repeated at a given level, this field indicates the repetition count for this particular test.

3.31.6.1.14 Use of the Observation Object

At least one occurrence of Observation below Control/Calibration:

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
observation_id	CE	R	[1..1]	The test identifier, preferably coded with LOINC
value	PQ	C	[0..1]	The observation result, if expressed quantitatively (i.e., a numerical value with units).
qualitative_value	CV	C	[0..1]	The observation result, if expressed qualitatively.
method_cd	CS	R	[1..1]	Origin of the result. Coded in table 36 of POCT1-A, Annex B. This LPOCT Profile authorizes only these values: **C** = Calculated (The value was calculated)

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
				D = Default (The value is a default value) **E** = Estimated **I** = Input (The value was externally input to the POCRG) **M** = Measured (The value was measured on the POCRG)
status_cd	CS	R	[1..1]	Status of the result. Coded in table 36 of POCT1-A, Annex B. This LPOCT Profile authorizes only these values for patient-related results: **A** = Accepted **D** = Discarded **R** = Rejected
interpretation_cd	CS	C	[0..1]	Interpretation of the result (abnormal flags). Coded in table 38 of POCT1-A, Annex B (See section Y.6.1.3 above)
normal_lo-hi_limit	IVL<PQ>	RE	[0..1]	The low and high limit range for a normal result
critical_lo-hi_limit	IVL<PQ>	RE	[0..1]	The low and high limit range outside which clinical review is required

Condition predicate for fields ***value***, ***qualitative_value*** and ***interpretation_cd***: Same as in section Y.6.1.3 above.

3.31.6.1.15 Use of the Note Object Related to the Observation Object

Zero or one occurrence of this object may appear below an observation. The note is a comment related to the observation.

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
text	ST	R	[1..1]	Comment of the observation

3.31.6.1.16 Use of the Operator Object

One and only one occurrence.

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
operator_id	ST	R	[1..1]	A unique identifier for the operator
name	PN	RE	[0..1]	Operator's name. Required if available on the POCRG.

3.31.6.1.17 Use of the Reagent Object

Zero or one occurrence.

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
name	ST	RE	[0..1]	The manufacturer's name for the reagent
lot_number	CV	R	[1..1]	The lot number of reagent used
expiration_date	TS	RE	[0..1]	The date past which the reagent should not be used

3.31.6.1.18 Use of the Note Object

Zero or more occurrences of this object may appear below the Service object. The note is a comment related to the service (i.e., the set of observations).

Attribute	Data Type	IHE Usage	IHE Cardinalities	Description
text	ST	R	[1..1]	Comment of the observation

3.31.7 Expected Actions

The POCDM receiving a message OBS.R01 (patient related observations) must check this set of observations against its own configuration rules (comparison with normal ranges, QC performed and OK, operator allowed to proceed, patient known in this point of care …). It then accepts or rejects this set of observations, and sends its reply in an Acknowledgement message. If the set of observations was accepted, the POCDM stores it in its data base. If the option "Supervision by laboratory" is supported, the POCDM initiates a Transaction LAB-32 with the Order Filler to forward this accepted set of observations.

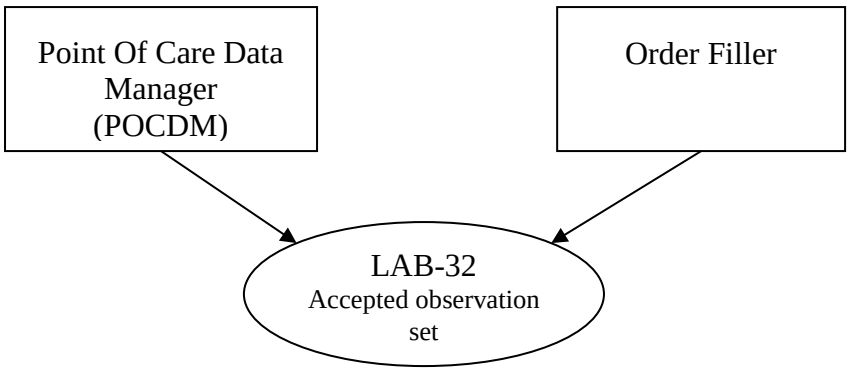
The POCDM receiving a message OBS.R02 (non-patient related observations) must check this set of observations against its own configuration rules. It then accepts or rejects this set of observations, and sends its reply in an Acknowledgement message. If the set of observations (QC or calibration results) was accepted, the POCDM stores it in its data base.

3.32 Accepted Observation Set (LAB-32)

3.32.1 Scope

This transaction is used within LPOCT Profile with the option "Supervision by laboratory": The POCDM forwards all accepted sets of patient observations to the Order Filler.

3.32.2 Use Case Roles



Actor: POCDM

Role: Forwards to the Order Filler each set of observations accepted for a patient specimen. Waits for the acknowledgement of this set of observations and stores the filler order number that it contains.

Actor: Order Filler

Role: Receives the set of patient observations, and according to the trigger event, either stores this set in an existing order, or generates a new order for it. In either case it will return the filler order number in the associated acknowledgement sent back to the POCDM.

3.32.3 Referenced Standard

POCT1-A: Observation Reporting Interface (ORI) defined in Appendix C of this standard. The POCT1-A standard names "***Observation Reviewer***" the IHE **POCDM** Actor, and names "***Observation Recipient***" the IHE **Order Filler** Actor.

HL7® v2.5: The ORI of POCT1-A relies on HL7® v2.5 messages structures ORU defined in chapter 7 of the HL7® standard.

All implementation rules and notes specified in the present Volume 2 of the IHE Laboratory Technical Framework fully apply to the messages of this transaction LAB-32. More precisely:

- Section 2.2 "HL7® profiling conventions"
- Section 2.3 "HL7® implementation notes"
- Section 3 "Common message segments for Laboratory Technical Framework". This section provides the common description of segments MSH, MSA, NTE, ERR, PID, that are also applicable to this transaction LAB-32.

3.32.4 Interaction Diagram

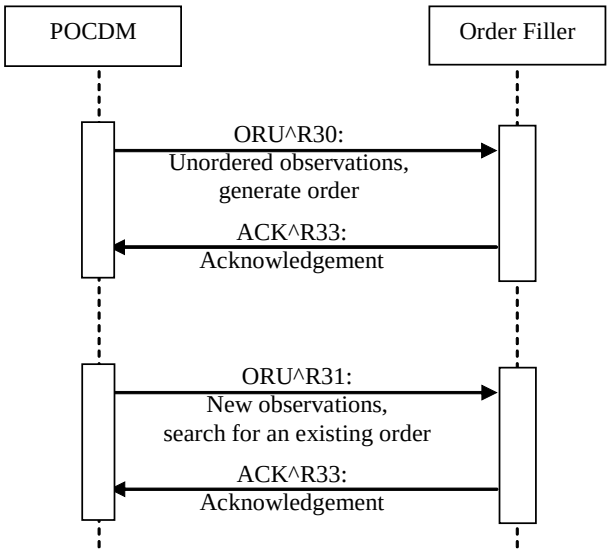


Figure 3.32.4.1: Interaction diagram for [LAB-32]

Transaction LAB-32 offers two distinct message structures to support the various use cases described in Volume 1:

- ORU^R30 (Unordered observations) is used in part 4 of scenarios 5.5.1 and 5.5.3, as well as in part 2 of scenario 5.5.4. The Order Filler SHALL generate a new order when receiving this message.
- ORU^R31 is used in part 4 of scenario 5.5.2: The POCDM instructs the Order Filler to match an existing order to store the observations.

The acknowledgement to both message structures is ACK^R33. This acknowledgement is an application acknowledgement that sends back the filler order number of the order generated or matched by the Order Filler, to store this set of POCT results.

Note 5: The trigger event ORU^R32 “preordered observations” described in POCT1-A’s ORI, is not part of the IHE LPOCT Profile. As explained in Volume 1 of this profile, section 1.4 “Relationship to real world architectures, and in Volume 2a, section 3.2.5.2, Note 1, this event corresponds to the normal scheduled workflow and is supported by the two IHE profiles LSWF and LDA.

3.32.5 Trigger Events

The POCDM integrates a set of point of care observations for a patient, received from a POCRG on LAB-31. The option “Supervision by laboratory” being supported, this event triggers a message of LAB-32 that sends these observations to the Order Filler.

If the indication “existing order” is present in the set of observations, the message is ORU^R31, otherwise the message is ORU^R30.

3.32.6 Message Semantics

3.32.6.1 Common Static Definition for ORU^R30 and ORU^R31

575

Table 3.32.6.1-1: Static Definition for ORU^R30 and ORU^R31

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R	[1..1]	2
PID	Patient Identification	R	[1..1]	3
ORC	Common Order information	R	[1..1]	4
OBR	Observation Request	R	[1..1]	4
[{NTE}]	Notes or Comments for order/Result	RE	[0..1]	4
[{	--- RESULT begin	O	[0..*]	
OBX	Observation related to OBR	R	[1..*]	7
[{NTE}]	Comment of the result	C	[0..1]	2
}]	--- RESULT end			

3.32.6.1.1 Usage of MSH segment

MSH-9 – Message Type, shall have its three components valued as follows:

580
- ORU^R30^ORU_R30 for the unordered point of care observations
- ORU^R31^ORU_R30 for the point of care observations to match with a possibly existing order

3.32.6.1.2 Usage of ORC Segment

The common definition of segment ORC in Volume 2 – section 3.7, does not apply to this
585 LPOCT Integration Profile: The ORU^R30 message structure instructs the recipient to generate the order, and the ORU^R31 message instructs to match an existing order, without identifying it.

Hence, the usage definition of ORC segment within this LPOCT Profile, below:

Table 3.32.6.1.2-1: ORC Segment

SEQ	LEN	DT	Usage	Card.	TBL #	ITEM#	Element name
1	2	ID	R	[1..1]	0119	00215	Order Control
2	22	EI	X	[0..0]		00216	Placer Order Number
3	22	EI	C	[0..0]		00217	Filler Order Number
4	22	EI	X	[0..0]		00218	Placer Group Number
5	2	ID	X	[0..0]	0038	00219	Order Status
7	200	TQ	X	[0..0]		00221	Quantity/Timing

SEQ	LEN	DT	Usage	Card.	TBL #	ITEM#	Element name
8	200	EIP	X	[0..0]		00222	Parent
9	26	TS	X	[0..0]		00223	Date/Time of Transaction
10	250	XCN	X	[0..0]		00224	Entered By
11	250	XCN	X	[0..0]		00225	Verified By
17	250	CE	X	[0..0]		00231	Entering Organization
20	250	CE	X	[0..0]	0339	01310	Advanced Beneficiary Notice Code
21	250	XON	RE	[0..1]		01311	Ordering Facility Name
25	250	CWE	X	[0..0]		01473	Order Status Modifier
26	60	CWE	X	[0..0]	0552	01641	Advanced Beneficiary Notice Override Reason
27	26	TS	X	[0..0]		01642	Filler's Expected Availability Date/Time

ORC-1 Order Control (ID), required. This field shall be valued to "NW" (new order) both in ORU^R30 and ORU^R31 message structures.

ORC-3 Filler Order Number (EI): This LPOCT Profile applies the condition predicate specified by POCT1-A: "*The POCDM may supply an external identifier in this field that other systems can use to reference this result set. This specification places no restrictions on the format or content of this field's value. For example, some POCDM might expose a database key in this field while others might use a combination of Device name, serial number and the timestamp of the result as the unique external identifier*".

ORC-21 Ordering Facility Name (XON), required but may be empty (RE).

For this LPOCT Profile, this field contains the facility (ward) where this point of care observation set has been performed. These three components shall be valued:

- 1st = Organization name.
- 7th = Identifier Type Code with the value "FI", which means "Facility ID" as stated by HL7® table n° 0203.
- 10th = Organization Identifier.

  Example: Urology^^^^^^FI^^^UR01

3.32.6.1.3 Usage of OBR Segment

Table 3.32.6.1.3-1: OBR Segment

SEQ	LEN	DT	Usage	Card.	TBL #	ITEM#	Element name
2	22	EI	X	[0..0]		00216	Placer Order Number
3	22	EI	X	[O..0]		00217	Filler Order Number
4	250	CE	R	[1..1]		00238	Universal Service Identifier
5	2	ID	X	[0..0]		00239	Priority – OBR

SEQ	LEN	DT	Usage	Card.	TBL #	ITEM#	Element name
6	26	TS	X	[0..0]		00240	Requested Date/Time
7	26	TS	X	[0..0]		00241	Observation Date/Time
8	26	TS	X	[0..0]		00242	Observation End Date/Time
9	20	CQ	X	[0..0]		00243	Collection Volume
10	250	XCN	X	[0..0]		00244	Collector Identifier
11	1	ID	R	[1..1]	0065	00245	Specimen Action Code
12	250	CE	X	[0..0]		00246	Danger Code
13	300	ST	X	[0..0]		00247	Relevant Clinical Information
14	26	TS	X	[0..0]		00248	Specimen Received Date/Time
15	300	SPS	RE	[0.1]		00249	Specimen Source or Segment SPM
16	250	XCN	RE	[0..1]		00226	Ordering Provider
17	250	XTN	X	[0..0]		00250	Order Callback Phone Number
18	60	ST	X	[0..0]		00251	Placer Field 1
19	60	ST	X	[0..0]		00252	Placer Field 2
20	60	ST	X	[0..0]		00253	Filler Field 1
21	60	ST	X	[0..0]		00254	Filler Field 2
22	26	TS	X	[0..0]		00255	Results Rpt/Status Chng – Date/Time
23	40	MOC	X	[0..0]		00256	Charge to Practice
24	10	ID	X	[0..0]	0074	00257	Diagnostic Serv Sect ID
25	1	ID	R	[1..1]	0123	00258	Order Result Status
26	400	PRL	X	[0..0]		00259	Parent Result
27	200	TQ	X	[0..0]		00221	Quantity/Timing
28	250	XCN	X	[0..0]		00260	Result Copies To
29	200	EIP	X	[0..0]		00261	Parent
30	20	ID	X	[0..0]	0124	00262	Transportation Mode
31	250	CE	X	[0..0]		00263	Reason for Study
32	200	NDL	C	[0..1]		00264	Principal Result Interpreter
33	200	NDL	X	[0..0]		00265	Assistant Result Interpreter
34	200	NDL	RE	[0..0]		00266	Technician
37	4	NM	X	[0..0]		01028	Number of Sample Containers *
38	250	CE	X	[0..0]		01029	Transport Logistics of Collected Sample
39	250	CE	X	[0..0]		01030	Collector's Comment *
40	250	CE	X	[0..0]		01031	Transport Arrangement Responsibility
41	30	ID	X	[0..0]	0224	01032	Transport Arranged
42	1	ID	X	[0..0]	0225	01033	Escort Required
43	250	CE	X	[0..0]		01034	Planned Patient Transport Comment
44	250	CE	X	[0..0]	0088	00393	Procedure Code
45	250	CE	X	[0..0]	0340	01316	Procedure Code Modifier
46	250	CE	X	[0..0]	0411	01474	Placer Supplemental Service Information
47	250	CE	X	[0..0]	0411	01475	Filler Supplemental Service Information
48	250	CWE	X	[0..0]	0476	01646	Medically Necessary Duplicate Procedure

SEQ	LEN	DT	Usage	Card.	TBL #	ITEM#	Element name
							Reason.
49	2	IS	X	[0..0]	N	01647	Result Handling

OBR-4 Universal Service Identifier (CE): This field identifies either a battery (panel) or an individual test. The first sub-field (the code), and the third (the coding system) are required.

OBR-11 Specimen Action Code (ID): This required field will be valued to 'O' (Specimen obtained by service other than lab).

OBR-15 Specimen source (CM): This field is required if available within LPOCT Profile, because the messages of this profile do not embed any SPM segment, given that very little information is needed on the specimen in point of care testing. This profile applies the POCT1-A recommendations of use for this field. The following components should be valued:

- 1st component: **Specimen Source Name or Code (CWE)**, called "Specimen Type" in POCT1-A. Codes are given by table 107 in POCT1-A.
- 4th component: **Body Site (CWE)**, called "Location" in POCT1-A. Code are given by table 108 in POCT1-A.
- 7th component: **Specimen Role (CWE)**, valued to 'P' (Patient specimen).

OBR-16 Ordering Provider (XCN): This field is required if available (RE). The POCDM shall value it with the ordering physician if it knows this information.

OBR-25 Order Result Status (ID): The set of observations is considered as reviewed (i.e., technically validated) either automatically or interactively by the POCDM application (called the Observation Reviewer in POCT1-A). Therefore the status shall be valued to "F" (Final results).

OBR-32 Principal Interpreter (NDL): The field identifies who validated (reviewed) the results, and when this technical validation was performed. It shall be valued if this review has been performed interactively by a human reviewer using the POCDM Actor; in this case only the two first components are required:

- Name (CNN):
  - First sub-subcomponent = ID number of the reviewer
  - Second sub-component = Family name
  - Third component = Given name
- Stat Date/Time (TS): Date/Time of the review.

OBR-34 Technician (NDL): The field is required if available (RE). It identifies the operator who produced the set of observations on the point of care device (the actor POCRG). It also locates the point of care, room, bed, facility, and dates this production. The following components are to be valued if the information is known:

1. 1st component: Name (CNN):
   - First sub-subcomponent = ID number of the reviewer

- Second sub-component = Family name
- Third component = Given name

- 2nd component: Stat Date/Time (TS): Date/Time of the testing.
- 4th component: Point Of Care (IS)
- 5th component: Room (IS)
- 6th component: Bed (IS)
- 7th component: Facility (HD)

3.32.6.2 Static Definition for ACK^R33: Acknowledgement Message

This message sent by the Order Filler to the POCDM is the acknowledgement message for both ORU^R30 and ORU^R31 messages.

Table 3.32.6.2-1: static definition for ACK^R33

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R	[1..1]	2
MSA	Message Acknowledgement	R	[1..1]	2
[{ERR}]	Error	C	[0..1]	2

MSH-9 – Message Type, shall have its three components valued "**ACK^R33^ACK**"

3.32.6.2.1 Usage of MSA Segment

Table 3.32.6.2.1-1: MSA - Message Acknowledgement

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	2	ID	R	[1..1]	0008	00018	Acknowledgement code
2	20	ST	R	[1..1]		00010	Message Control Id
3	80	ST	R	[0..0]		00020	Text Message
5			X	[0..0]		00022	Delayed Acknowledgment Type
6	250	CE	X	[0..0]	0357	00023	Error Condition

The general specification of use of this segment by the IHE Laboratory Technical Framework is given in section 3.2 of the present volume 2.

The particularity of use in the context of the Order Filler acknowledging a POCT observation set to the POCDM is as follows:

MSA-3 – Text Message (ST), is usage R (required). This field contains the filler order number sent by the Order Filler to the POCDM.

3.32.7 Expected Actions

When receiving an ORU^R30, the Order Filler performs the following sequence of actions:

1. It generates a new order to store this set of point of care observations within.
2. It sends back to the POCDM the acknowledgement message ACK^R33, including the filler order number.
3. Using Transaction LAB-2 of LSWF Profile, the Order Filler propagates this new order to the Order Placer, and requires a placer order number for it. The placer order number is sent back by the Order Placer to the Order Filler.
4. The Order Filler stores the placer order number within the order in its database.

When receiving an ORU^R31, the Order Filler performs the following sequence of actions:

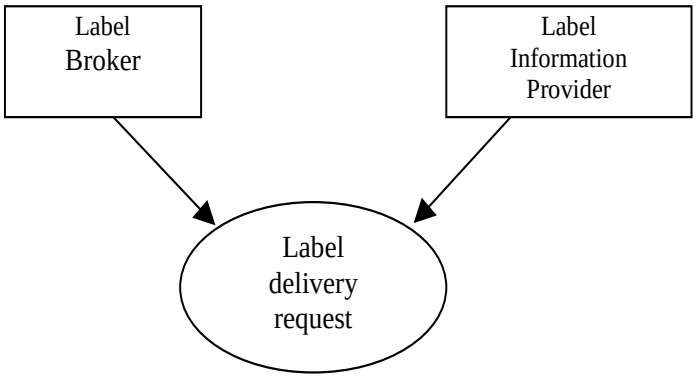
1. It tries to match an existing order in its data base, corresponding to this set of observations. The criteria used may depend upon site-defined policies. They should include the patient, the ordering provider, the facility where the point of care tests was performed, the date-time of the observations and the ordering provider.
2. If no order can be matched, the Order Filler proceeds as if it had received an ORU^R30 (see the sequence of actions above).
3. If an order is matched, the Order Filler stores the results in this order, and acknowledges the order to the POCDM, sending back the filler order number in the acknowledgement.
4. Using Transaction LAB-1 of LSWF Profile, the Order Filler notifies the arrival of the POCT results to the Order Placer.

3.33 Label Delivery Request (LAB-61)

3.33.1 Scope

This transaction is used by the Label Information Provider to send label delivery instructions to the Label Broker.

3.33.2 Use Case Roles



Actor: Label Broker

Role: The Label Broker receives labeling instructions to issue the specimen container labels and stick them on the appropriate containers.

Actor: Label Information Provider

Role: The Label Information Provider transmits the labeling instructions to the Label Broker.

3.33.3 Referenced Standard

HL7® v2.5, Chapter 4

3.33.4 Interaction Diagram

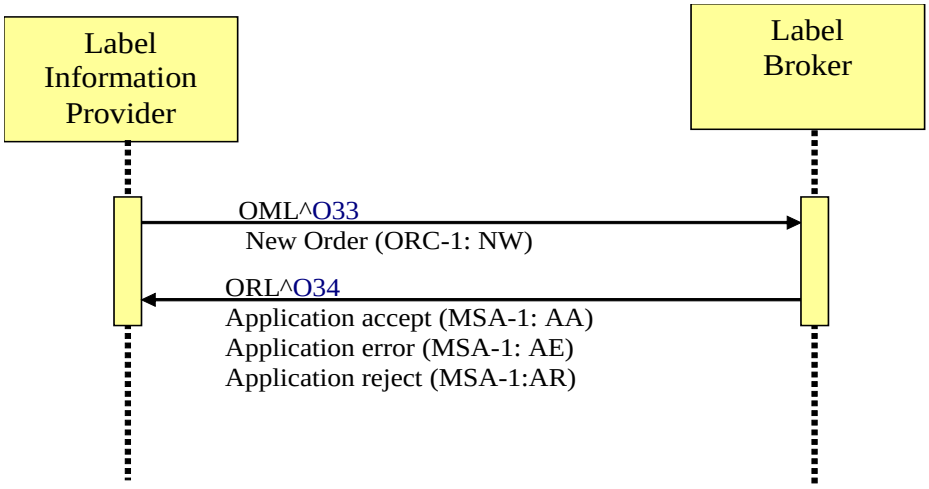


Figure 3.33.4-1: Interaction diagram for [LAB-61]

705

3.33.4.1 Message Static Definitions

This transaction contains the messages used to send labeling instructions from the Label Information Provider to the Label Broker.

3.33.4.2 Trigger Events

710 OML (O33): Label information sent by the Label Information Provider.

ORL (O34): Application acknowledgement of the Label information sent by Label Broker.

3.33.4.3 Message Semantics

Table 3.33.4.3-1: OML^O33

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R	[1..1]	2
[	--- PATIENT begin	R	[1..1]	
PID	Patient Identification	R	[1..1]	3
[PV1]	Patient Visit	RE	[0..1]	3
]	--- PATIENT end			
{	--- SPECIMEN begin	R	[1..*]	
SPM	Specimen	R	[1..1]	7
[{SAC}]	Specimen Container	O	[0..*]	
{	--- ORDER begin	R	[1..*]	
ORC	Common Order (for one battery)	R	[1..1]	4
[{TQ1}]	Timing Quantity	RE	[0..1]	4
[	--- OBSERVATION REQUEST begin	O	[O..1]	
OBR	Observation Request	R	[1..1]	4

Segment	Meaning	Usage	Card.	HL7 chapter
[TCD]	Test Code Details	O	[0..1]	13
[{OBX}]	Observation Result	O	[0..*]	7
]	--- OBSERVATION REQUEST end			
}	--- ORDER end			
}	--- SPECIMEN end			

MSH-9 - Message Type (MSG) shall have its three components respectively valued to "OML", "O33" and “OML_O33”.

This message carries the specimen container labeling instructions in the SPECIMEN segment group: The SPM segment contains the specimen ID (SPM-2) , specimen type (SPM-4), specimen source site (SPM-8), specimen collection amount (SPM-12), container type (SPM-27)… Optionally, the SAC segment may be used to deliver additional information on the physical container to be selected by the Label Broker.

Table 3.33.4.3-2: ORL^O34

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	R	[1..1]	2
MSA	Message Acknowledgement	R	[1..1]	2
[{ERR}]	Error	C	[0..*]	2
[	--- RESPONSE begin	O	[0..1]	
[PID]	Patient Identification	O	[0..1]	3
{	--- SPECIMEN begin	O	[0..*]	
SPM	Specimen	R	[1..1]	7
[{SAC}]	Specimen Container	O	[0..*]	13
[{	--- ORDER begin	O	[0..*]	
ORC	Common Order	R	[1..1]	4
[{TQ1}]	Timing/Quantity	RE	[0..1]	4
[OBR]	Observation Request	R	[1..1]	4
}]	--- ORDER end			
}	--- SPECIMEN end			
]	--- RESPONSE end			

MSH-9 - Message Type (MSG) shall have its three components respectively valued to "ORL", "O34" and “ORL_O34”.

Condition predicate for use of the ERR segment:

The ERR segment SHALL be used whenever the Label Broker does not accept the labeling instruction (MSA-1 = AE or AR)

3.33.4.4 OBR Segment

Table 3.33.4.4-1: OBR Segment

SEQ	LEN	DT	Usage	Card.	TBL #	ITEM#	Element name
1	4	SI	O	[0..1]		00237	Set ID – OBR
2	22	EI	R	[1..1]		00216	Placer Order Number
3	22	EI	RE	[0..1]		00217	Filler Order Number
4	250	CE	R	[1..1]		00238	Universal Service Identifier
5	2	ID	X	[0..0]		00239	Priority – OBR
6	26	TS	X	[0..0]		00240	Requested Date/Time
7	26	TS	X	[0..0]		00241	Observation Date/Time #
8	26	TS	X	[0..0]		00242	Observation End Date/Time #
9	20	CQ	X	[0..0]		00243	Collection Volume *
10	250	XCN	O	[0..*]		00244	Collector Identifier *
11	1	ID	RE	[0..1]	0065	00245	Specimen Action Code *
12	250	CE	X	[0..0]		00246	Danger Code
13	300	ST	X	[0..0]		00247	Relevant Clinical Information
14	26	TS	X	[0..0]		00248	Specimen Received Date/Time *
15	300	SPS	X	[0..0]		00249	Specimen Source
16	250	XCN	R	[1..1]		00226	Ordering Provider
17	250	XTN	RE	[0..2]		00250	Order Callback Phone Number
18	60	ST	X	[0..0]		00251	Placer Field 1
19	60	ST	X	[0..0]		00252	Placer Field 2
20	60	ST	X	[0..0]		00253	Filler Field 1 +
21	60	ST	X	[0..0]		00254	Filler Field 2 +
22	26	TS	X	[0..0]		00255	Results Rpt/Status Chng - Date/Time +
23	40	MOC	X	[0..0]		00256	Charge to Practice +
24	10	ID	C	[0..1]	0074	00257	Diagnostic Serv Sect ID
25	1	ID	X	[0..0]	0123	00258	Result Status +
26	400	PRL	X	[0..0]		00259	Parent Result +
27	200	TQ	X	[0..0]		00221	Quantity/Timing
28	250	XCN	O	[0..*]		00260	Result Copies To
29	200	EIP	X	[0..0]		00261	Parent
30	20	ID	X	[0..0]	0124	00262	Transportation Mode
31	250	CE	O	[0..1]		00263	Reason for Study
32	200	NDL	O	[0..1]		00264	Principal Result Interpreter +
33	200	ND	O	[0..1]		00265	Assistant Result Interpreter +

SEQ	LEN	DT	Usage	Card.	TBL #	ITEM#	Element name
		L					
34	200	NDL	O	[0..1]		00266	Technician +
35	200	NDL	O	[0..1]		00267	Transcriptionist +
36	26	TS	O	[0..1]		00268	Scheduled Date/Time +
37	4	NM	O	[0..1]		01028	Number of Sample Containers *
38	250	CE	O	[0..1]		01029	Transport Logistics of Collected Sample *
39	250	CE	O	[0..1]		01030	Collector's Comment *
40	250	CE	X	[0..0]		01031	Transport Arrangement Responsibility
41	30	ID	X	[0..0]	0224	01032	Transport Arranged
42	1	ID	X	[0..0]	0225	01033	Escort Required
43	250	CE	X	[0..0]		01034	Planned Patient Transport Comment
44	250	CE	O	[0..1]	0088	00393	Procedure Code
45	250	CWE	O	[0..1]	0340	01316	Procedure Code Modifier
46	250	CE	O	[0..1]	0411	01474	Placer Supplemental Service Information
47	250	CE	O	[0..1]	0411	01475	Filler Supplemental Service Information
48	250	CWE	X	[0..0]	0476	01646	Medically Necessary Duplicate Procedure Reason.
49	2	IS	O	[0..1]	0507	01647	Result Handling

3.33.5 Issuing additional tubes or labels carrying the same specimen ID

Some use cases often require that for the same request, more than one tube or label with the same SPECIMEN_ID has to be used to perform request orders : this situation is due to the Order Filler or Order Placer specimens collection policy.

In order to explain how many labels or tubes with the same SPECIMEN_ID are to be printed, the SAC segment is used for each additional label/tube. The Laboratory Information Provider shall provide, in the OML_O33 message, immediately after the related SPM segment, as many SAC segment as there are additional labels requested. Refer to LAB TF-2.x: Table C.8 for details.

3.33.6 Expected Actions

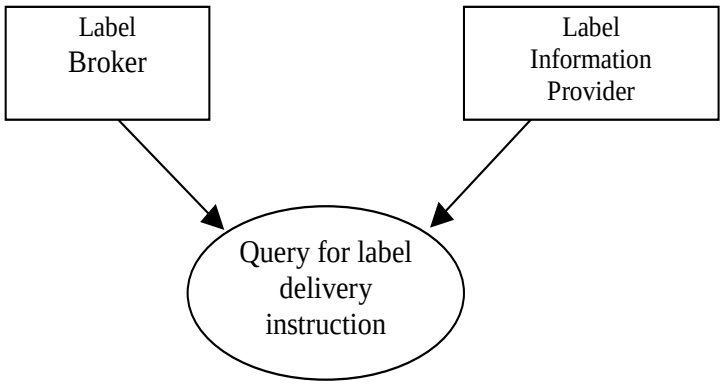
The OML message with Order Control Code ‘NW’ received from the Label Information Provider, contains the specimen container labeling instructions for the Label Broker. The Label Broker will reply with an ORL^O34 message with either “Accept” (MSA-1 = AA) or “Reject” (MSA-1 = AR) or “Error” (MSA-1 = AE).

3.34 Query for Label Delivery Instruction (LAB-62)

3.34.1 Scope

This transaction is used by the Label Broker to query the specimen container labeling instructions from the Label Information Provider.

3.34.2 Use Case Roles



Actor: Label Broker

Role: The Label Broker sends a query to the Label Information Provider in order to get the labeling instructions related to the laboratory test orders for a patient.

Actor: Label Information Provider

Role: The Label Information Provider responds to the query with the labeling instructions.

3.34.3 Referenced Standard

HL7® version 2.5:

3.34.4 Interaction Diagram

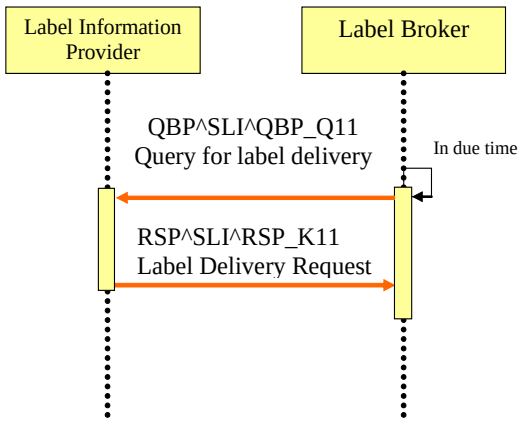


Figure 3.34.4-1: Interaction diagram for [LAB-62]

3.34.5 Message Static Definitions

3.34.5.1 Trigger Events

QBP(Q11) : Query for specimen container labeling instructions sent by the Label Broker.
RSP(K11) : Response including the labeling instructions sent by the Label Information Provider.

3.34.5.2 Message Semantics

Table 3.34.5.2-1: QBP^SLI^QBP_Q11

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	R	[1..1]	2
[{SFT}]	Software Segment	O	[0..*]	2
QPD	Query Parameter Definition	R	[1..1]	5
RCP	Response Control Parameter	R	[1..1]	5
[DSC]	Continuation Pointer	O	[0..1]	2

MSH-9 - Message Type (MSG) shall be valued as: QBP^SLI^QBP_Q11

Table 3.34.5.2-2: RSP^SLI^RSP_K11

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	R	[1..1]	2
[{SFT}]	Software Segment	O	[0..*]	2
MSA	Message Acknowledgement	R	[1..1]	2
[ERR]	Error	O	[0..1]	2
QAK	Query Acknowledgement	R	[1..1]	5
QPD	Query Parameter Definition	R	[1..1]	5
[	--- PATIENT begin	C	[0..1]	
PID	Patient Identification	R	[1..1]	3
PV1	Patient Visit	O	[0..1]	3
[{OBX}]	Observation related to the patient	O	[0..*]	7
{	--- SPECIMEN begin	R	[1..*]	
SPM	Specimen	R	[1..1]	7
[{OBX}]	Observation related to specimen	O	[0..*]	7
[{SAC}]	Specimen Container	O	[0..*]	13
{	--- ORDER begin	R	[1..*]	
ORC	Common Order	R	[1..1]	4
[{TQ1}]	Timing/Quantity	RE	[0..1]	4
[	--- OBSERVATION REQUEST begin	O	[0..1]	
OBR	Observation Request	R	[1..1]	4

Segment	Meaning	Usage	Card.	HL7 chapter
[TCD]	Test Code Details	O	[0..1]	13
[{OBX}]	Observation Result	O	[0..*]	7
]	--- OBSERVATION REQUEST end			
}	--- ORDER end			
}	--- SPECIMEN end			
]	--- PATIENT end			

MSH-9 - Message Type (MSG) shall have its two first components respectively valued to "RSP" and "K11".

Condition predicate for PATIENT segment group: This segment group is present if and only if the LIP has labeling instructions available matching the query criteria. If not the reply message shall contain only the first segments from MSH to QPD, the QAK segment indicating with QAK-2 “Query Response Status” valued “NF” (i.e., no data found, no error) that there was no available data matching the query parameters.

3.34.5.3 QPD Segment

Table 3.34.5.3-1: QPD segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	60	CE	R	[1..1]		01375	Message Query Name
2	32	ST	R	[1..1]		00696	Query Tag
3	80	CK	C	[0..1]		00105	Patient ID
4	250	CX	C	[0..1]		00149	Patient Visit Number
5	22	EI	C	[0..1]		00218	Placer Group Number
6	22	EI	C	[0..1]		00216	Placer Order Number,
7	22	EI	C	[0..1]		00217	Filler Order Number
8	53	DR	C	[0..1]			Search Period

QPD-1 Message Query Name (CE), required

Must be valued ”SLI^Specimen Labeling Instructions^IHE_LABTF”

QPD-2 Query Tag (ST), required

Unique to each query message instance. This identifies the query instance. It is used to match the response with the query.

QPD-3 Patient Identifier, conditional

Contains a patient unique identifier, as defined in PID-3.

QPD-4 Patient Visit Number, conditional

Contains a patient visit number, as defined in PV1-19.

QPD-5 Placer Group Number, conditional
Contains a placer group number, as defined in ORC-4.

QPD-6 Placer Order Number, conditional
Contains a placer order number, as defined in transaction LAB-1 (OBR-2).

QPD-7 Filler Order Number, conditional
Contains a filler order number, as defined in transaction LAB-1.(OBR-3)

Condition predicate: At least one of the fields QPD-3, QPD4, QPD-5, QPD-6, QPD-7 must be valued. In case QPD-3 or QPD-4 is used and there is more than one pending test order for the patient id or the visit number, it is the responsibility of the application implementing the Label Information Provider Actor to decide whether to pick up one or all of the pending orders. The business rules governing this decision are out of the scope of this Integration Profile.

QPD-8 Search Period (DR), conditional

This field contains a range of date/times

HL7® Component Table - DR – Date/Time Range

SEQ	LEN	DT	OPT	TBL#	COMPONENT NAME	COMMENTS	SEC.REF.
1	26	TS	O		Range Start Date/Time		2.A.77
2	26	TS	O		Range End Date/Time		2.A.77

Condition predicate: This criterion can be used when no order identifier is available, that is, when field QPD-5, QPD-6, QPD-7 are empty. QPD-8 is used in conjunction with QPD-3 or QPD-4.

Use case: It happens that the patient comes to the specimen collection room on another day than the scheduled one. Therefore a range of dates is a convenient criterion if the only information brought by the patient is a patient identifier or a visit identifier.

3.34.5.4 RCP Segment

Table 3.34.5.4-1: RCP segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	1	ID	R	[1..1]	0091	00027	Query Priority
2	10	CQ	O	[0..1]	0126	00031	Quantity Limited Request
		NM					
		CE					
3	60	CE	R	[1..1]	0394	01440	Response Modality
7	256	ID	O	[0..*]		01594	Segment group inclusion

RCP-1 Query Priority(ID), required

Shall be fixed to "I" (=Immediate).

RCP-2 Quantity Limited Request (CQ), optional

As for the 1st component "Quantity"(NM), Number of records that will be returned in each increment of the response. If no value is given, the entire response will be returned in a single increment.

As for the 2nd component "Units"(CE), "RD"(=Records) is always set. If no value is given, the default is RD.

RCP-3 Response Modality (CE), required

Shall be fixed to "R" (=Realtime).

RCP-7 Segment group inclusion (ID), optional

Specifies those optional segment groups which are to be included in the response. If this field is not valued, all segment groups will be included.

3.34.6 Issuing additional tubes or labels carrying the same specimen ID

Some use cases often require that for the same request, more than one tube or label with the same SPECIMEN_ID has to be used to perform request orders : this situation is due to the Order Filler or Order Placer specimens collection policy.

In order to explain how many labels or tubes with the same SPECIMEN_ID are to be printed, the SAC segment is used for each additional label/tube. The Laboratory Information Provider shall provide, in the OML_O33 message, immediately after the related SPM segment, as many SAC segment as there are additional labels requested. Refer to LAB TF-2x: Table C.8 for details.

3.34.7 Expected Actions

The Label Information Provider parses the query parameters, and selects the appropriate pending test order(s) matching these parameters, according to its own business rules, and builds the response, which is sent back immediately to the Label Broker.

3.35 Laboratory Code Set Management (LAB-51)

3.35.1 Scope

This transaction is used by the Code Set Master Actor to distribute entire code sets to Code Set Consumer actors. A code set may contain battery, test and observation codes. This transaction is initiated on a scheduled based (e.g., weekly) or whenever the organization of the laboratory changes (e.g., because of the addition/removing of an instrument, specialties).

3.35.2 Use Case Roles

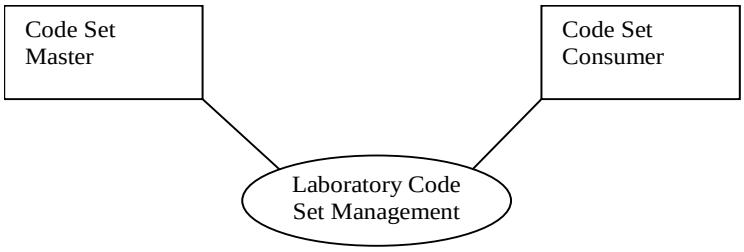


Figure 3.35.2-1: Use Case Roles for the Laboratory Code Set Management transaction

Actor: Code Set Master

Role: Sends a full code set.

Actor: Code Set Consumer

Role: Receives a code set, and notifies the Code Set Master of its acceptance or refusal.

3.35.3 Referenced Standard

HL7® 2.5.1 Chapter 8 (Master Files)

HL7® 2.5.1 Chapter 2 : 2.10.3 (Batch protocol), 2.15.2 (BHS segment), 2.15.3 (BTS segment)

3.35.4 Interaction Diagrams

The interaction diagrams show the message flow between a Code Set Master and a Code Set Consumer. Four messages are defined for this transaction:

- MFN^M08 – Master File Notification – Test/Observation (Numeric). This message is used for codes related to individual tests with numeric results. This message should not be used for battery or profile definitions. If the result of the test is a formulaic expression (a calculation) of other tests, MFN^M11 should be used instead of this message.
- MFN^M09 – Master File Notification – Test/Observation (Categorical). This message is used for codes related to individual tests with results that are NOT numeric. This message should not be used for battery or profile definitions. If the result of the test is a formulaic expression of other tests, MFN^M11 should be used instead of this message

- MFN^M10 – Master File Notification – Test/Observation Batteries. This message is used for codes that identify batteries or profiles. This message should not be used to for individual tests.
- MFN^M11 – Master File Notification – Test/Calculated Observations. This message is used for codes related to individual tests with calculated results. This message should not be used for battery or profile definitions.

In order to simplify the management of observation codes (OBX-3) and battery codes (OBR-4), the MFN^M08, MFN^M09 and MFN^M11 messages will be used to distribute observation codes only (OBX-3), and MFN^M10 will be used to distribute battery codes (OBR-4).

The definitions of atomic tests (M08, M09) shall in all cases precede the definitions of batteries and calculated tests (M10, M11).

3.35.4.1 Laboratory Code Set Management

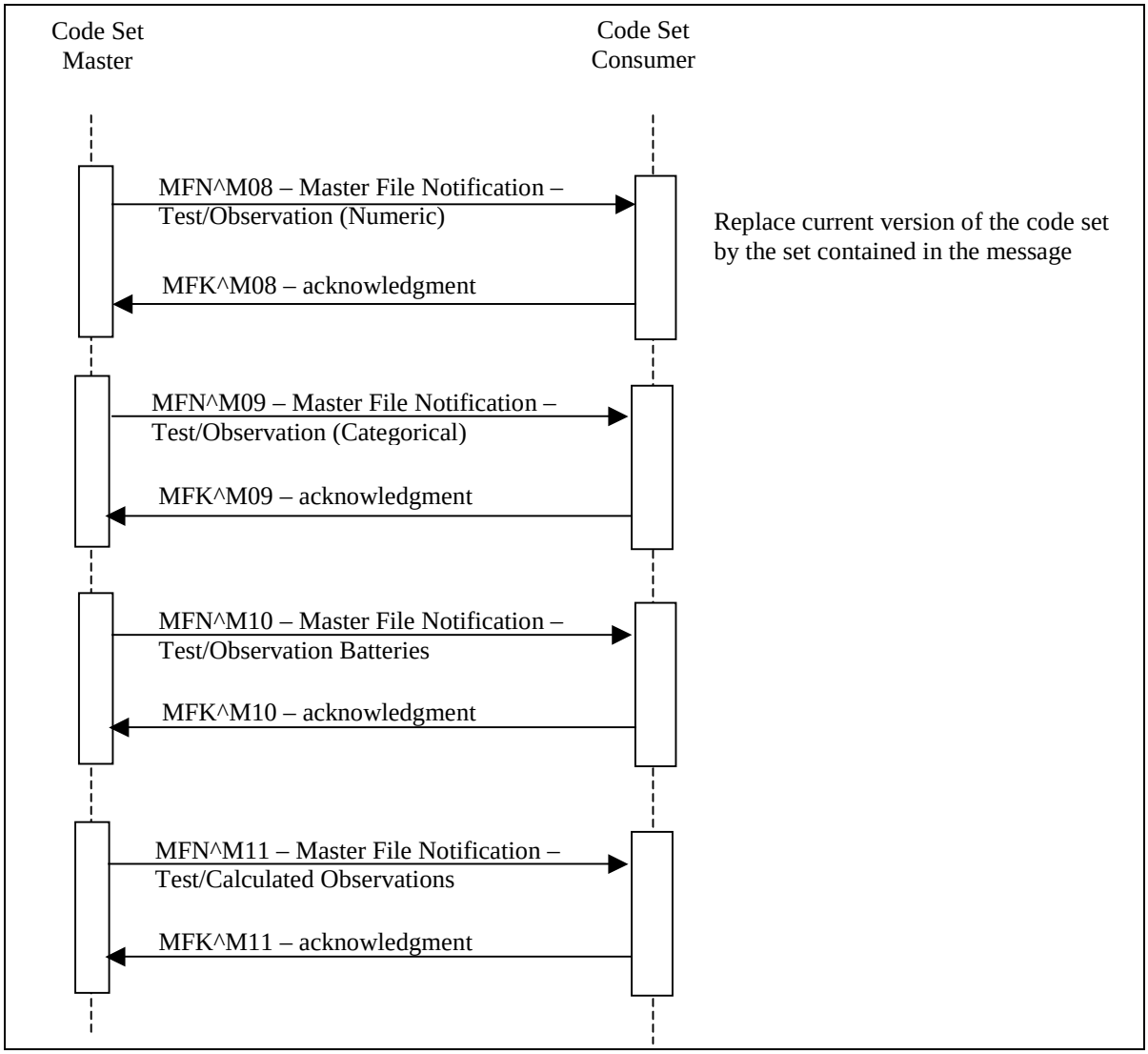


Figure 3.35.4.1-1: Interaction diagram for [LAB-51]

In order to fully synchronize the code set between the Code Set Master and the Code Set Consumer 4 messages shall be sent.

3.35.4.2 Laboratory Code Set Management with Batch Option

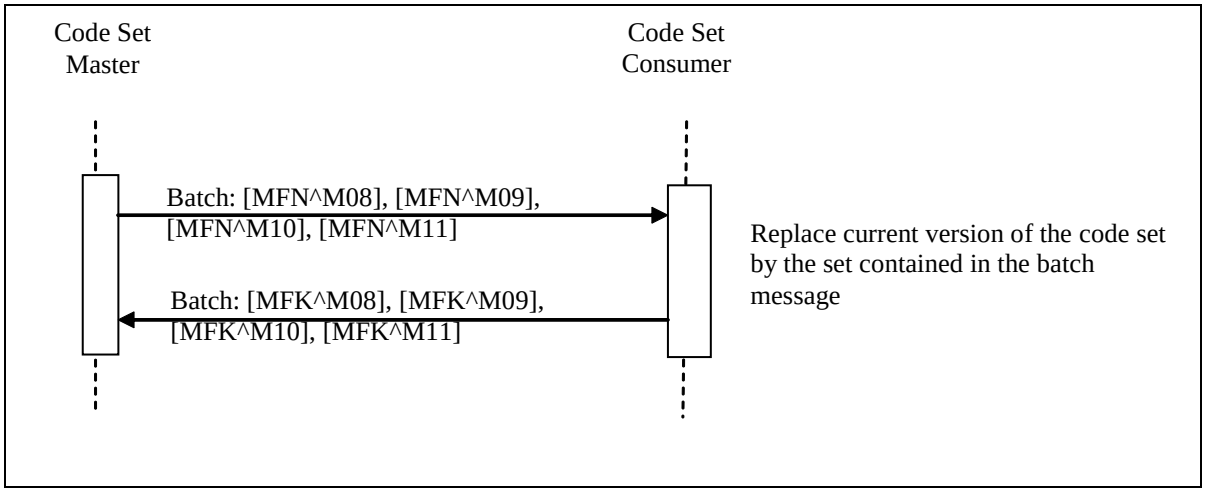


Figure 3.35.4.2-1: Interaction diagram for [LAB-51] using Batch Message Option

The Code Set Master sends a single batch containing 1 to 4 MFN messages, and the Code Set Consumer responds with a single batch acknowledgement containing the corresponding acknowledgement MFK messages.

3.35.5 Message Static Definitions

3.35.5.1 Trigger Events

MFN^M08 – the Code Set Master sends a full set of observation codes.

MFN^M09 – the Code Set Master sends a full set of non-numeric observation codes.

MFN^M10 – the Code Set Master sends a full set of battery codes.

MFN^M11 – the Code Set Master sends a full set of calculated observation codes.

3.35.5.2 Message Semantics

HL7® 2.5 Chapter 8 MFN^M08 message. Refer to HL7® Standard for general message semantics. The OM2 segment can be used to transport the Units of Measure if necessary.

Table 3.35.5.2-1: MFN^M08 static definition

Segment	Meaning	Usage	Card.	HL7
MSH	Message Header	R	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	R	[1..*]	8

Segment	Meaning	Usage	Card.	HL7
MFE	Master File Entry	R	[1..1]	8
OM1	General Segment	R	[1..1]	8
[OM2]	Numeric Observation Segment	O	[0..1]	8
[OM4]	Observations that Require Specimens	O	[0..1]	8
}	--- MASTER FILE ENTRY end			

See LAB TF-2x: Appendix C for the description of MFI and MFE segments.

MFI-1 Master File Identifier (CE), shall contain the value "OMA" (Numerical Observation Master File).

HL7® 2.5 Chapter 8 MFN^M09 message. Refer to HL7® Standard for general message semantics. The construction of the message is roughly the same as MFN^M08. The OM3 segment can be used to transmit categorical results for a test (such a "high"/"low", or "reactive"/"unreactive"/ "transactive") or to indicate a vocabulary for the results (e.g., SNOMED).

Table 3.35.5.2-2: MFN^M09 static definition

Segment	Meaning	Usage	Card.	HL7
MSH	Message Header	R	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	R	[1..*]	8
MFE	Master File Entry	R	[1..1]	8
OM1	General Segment	R	[1..1]	8
[	--- MF_TEST_CAT_DETAIL begin	O	[0..1]	8
OM3	Categorical Service/Test/Observation Segment	R	[1..1]	8
[{OM4}]	Observations that Require Specimens	O	[0..*]	8
]	--- MF_TEST_CAT_DETAIL end			
}	--- MASTER FILE ENTRY end			

HL7® 2.5 Chapter 8 MFN^M10 message. Refer to HL7® Standard for general message semantics. The construction of the message is roughly the same as MFN^M08.

Table 3.35.5.2-3: MFN^M10 static definition

Segment	Meaning	Usage	Card.	HL7
MSH	Message Header	R	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	R	[1..*]	8

Segment	Meaning	Usage	Card.	HL7
MFE	Master File Entry	R	[1..1]	8
OM1	General Segment	R	[1..1]	8
[	--- MF_TEST_BATT_DETAIL begin	RE	[0..1]	8
OM5	Observation Batteries	R	[1..1]	8
[{OM4}]	Observations that Require Specimens	O	[0..*]	8
]	--- MF_TEST_BATT_DETAIL end			
}	--- MASTER FILE ENTRY end			

See LAB TF-2x Appendix C for the description of MFI and MFE segments.

MFI-1 Master File Identifier (CE), shall contain the value "OMC" (Observation Batteries Master File).

HL7® 2.5 Chapter 8 MFN^M11 message. Refer to HL7® Standard for general message semantics. The construction of the message is roughly the same as MFN^M08. The OM6 segment can be used to detail the rule or formula used to determine the value of the test. The OM2 segment can be used to specify the units of measure if the formula results in a numeric value.

Table 3.35.5.2-4: MFN^M11 static definition

Segment	Meaning	Usage	Card.	HL7
MSH	Message Header	R	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	R	[1..*]	8
MFE	Master File Entry	R	[1..1]	8
OM1	General Segment	R	[1..1]	8
[				
OM6	Observation calculated from other observations	O	[0..1]	8
OM2	Numeric Observation Segment	O	[0..1]	8
]				
}	--- MASTER FILE ENTRY end			

See LAB TF-2X: Appendix C for the description of MFI and MFE segments.

MFI-1 Master File Identifier (CE), required, shall contain the value OMD (Calculated Observations Master File).

3.35.5.2.1 Master File Notification – Test/Observation (Numeric)

This message is used to transmit observation codes, i.e., codes sent in the OBX-3 field (Observation Identifier). Observations must have continuous values (data of type numeric, date, or time stamp).

3.35.5.2.2 Master File Notification – Test/Observation (Categorical)

This message is used to transmit the code of observations where the value is free text and other non-numeric data types.

3.35.5.2.3 Master File Notification – Test/Observation Batteries

This message is used to transmit battery codes, i.e., codes sent in the OBR-4 field (Universal Service Identifier).

3.35.5.2.4 Master File Notification – Test/Calculated Observation

This message is used to transmit the code of observations where the value is derived from one or more quantities or direct observations.

3.35.5.2.5 Acknowledgement Message

Applications that receive HL7® messages defined in the IHE Laboratory Technical Framework shall send acknowledgements using the HL7® original acknowledgement mode. The Master File Application Acknowledgment message is defined in HL7® 2.5 Chapter 8. The structure of the acknowledgement messages is the same for all acknowledgements:

Table 3.35.5.2.5-1: MFK^M08, MFK^M09, MFK^M10, MFK^M11 Static Definition

Segment	Meaning	Usage	Card.	HL7
MSH	Message Header	R	[1..1]	2
MSA	Acknowledgment	R	[1..1]	2
[{ERR}]	Error	C	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	C	[0..*]	8
MFA	Master File ACK Segment	R	[1..1]	8
}	--- MASTER FILE ENTRY end			

The construction of MSH, MSA and ERR segments is defined in section 3.1 of the IHE Laboratory Technical Framework, Volume II. The ERR segment shall be used in case of negative acknowledgement, i.e., when the receiving application sends an error on one Master File entry.

The MASTER FILE ENTRY segment group is conditional upon the presence of errors (see the description of field MFI-6). The segment group shall only be populated with MFA Segment for those master file entries that could NOT be accepted. If the entire batch can be accepted by the receiver then the acknowledgement message shall not contain any MFA segments.

3.35.5.3 OM1 – General Segment

Table 3.35.5.3-1: OM1 – General Segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	4	NM	R	[1..1]		00586	Sequence Number - Test/Observation Master File
2	250	CE	R	[1..1]		00587	Producer's Service/Test/Observation ID
3	12	ID	O	[0..*]	0125	00588	Permitted Data Types
4	1	ID	R	[1..1]	0136	00589	Specimen Required
5	250	CE	R	[1..1]		00590	Producer ID
7	250	CE	O	[0..*]		00592	Other Service/Test/Observation IDs for the Observation
8	200	ST	R	[1..*]		00593	Other Names
12	1	ID	O	[0..1]	0136	00597	Orderability
18	1	IS	R	[1..1]	0174	00603	Nature of Service/Test/Observation
19	250	CE	RE	[0..1]	99999	00604	Report Subheader
20	20	ST	RE	[0..1]		00605	Report Display order
30	250	CWE	O	[0..1]	0177	00615	Confidentiality Code
31	250	CE	O	[0...*]	9999	00616	Observations Required to Interpret the Observation

OM1-1 Sequence Number – Test/Observation Master File (NM), required, shall contain a sequence number from 1 to n (number of records).

OM1-2 MFN Producer's Service/Test/Observation ID (CE) is required. Only the first three sub-fields (Identifier, Text and Name of Coding System) are required. The last 3 components of the CE data type shall not be valued.

(MFN^M08 and MFN^M10 and MFN^M11 messages)

OM1-3 Permitted Data Types (ID), optional, should contain numerical, date or time stamp data types.

(MFN^M09 message)

OM1-3 Permitted Data Types (ID), optional, should contain data types other than numerical, date or time stamp.

OM1-4 Specimen Required (ID), required, contain the value `Y` if one or more specimen are required to obtain this observation, and `N` if a specimen is not required.

OM1-5 Producer ID (CE), required, uniquely identifies the service producing the observation. Only the first three sub-fields (Identifier, Text and Name of Coding System) are required.

OM1-7 Other Service/Test/Observation IDs for the Observation (CE) is optional and repeating. It can be used to send mapped/translated codes to the destination system. This field can be used to convey the mapping of local codes to reference code sets such as LOINC or SNOMED CT.

OM1-8 Other Names (ST), required, contains aliases or synonyms for the name in the context of the Order Placer. By default, this field can contain the same value as OM1-2 (2nd sub-field).

OM1-12 Orderability (ID), optional, indicates whether or not a service/test/observation is an orderable code. For example, blood differential count is usually an orderable "test," MCV, contained within the differential count, is usually not independently orderable.

Table 3.35.5.3-2: HL7® Table 0136 – Yes/No Indicator Values

Value	Description
Y	The service/test/observation is an orderable code
N	The service/test/observation is not orderable

(MFN^M08 and MFN^M09 messages)

OM1-18 Nature of Service/Test/Observation (IS), required, contains the value A (atomic observation).

(MFN^M10 message)

OM1-18 Nature of Service/Test/Observation (IS), required, contains the value P (battery consisting of one or many independent atomic observations), F (functional procedure) and S (superset of batteries or procedure ordered under a single code unit).

(MFN^M11 message)

OM1-18 Nature of Service/Test/Observation (IS), required, contains the value C (single observation calculated via a rule or formula from other independent observations).

OM1-19 Report Subheader (CE), required if known, contains an optional string that defines the preferred header under which this observation should be listed on a standard display.

OM1-20 Report Display Order (ST), required if known, contains an optional string that defines the absolute sort order in which this observation is presented in a standard report or display that contains the many observations.

OM1-30 Confidentiality Code (CWE), optional, contains the degree to which special confidentiality protection should be applied to the observation. For example, a tighter control may be applied to an HIV test than to a CBC. This field can especially be useful if all observations for the OM1 record can be treated in the same manner.

Table 3.35.5.3-3: HL7® Table 0177 – Confidentiality Code (Subset)

Value	Description
V	Very restricted

Value	Description
R	Restricted
U	Usual control

OM1-31 Observations Required to Interpret the Observation (CE), optional.

This field contains the list of supporting observations (e.g., patient temperature) needed by the laboratory to perform the ordered test.

Each of these supporting observations appears as a coded test that must have been sent ahead of the current test, in the same catalog, published through transaction LAB-51.

The observations specified here should be sent to the diagnostic service as OBX segments along with the order (OBR) segment in LAB-1 messages.

3.35.5.4 OM2 – Numeric Observation Segment

Table 3.35.5.4-1: OM2 – Numeric Observation Segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
2	250	CE	R	[1..1]		00627	Units of Measure
3	10	NM	RE	[0..*]		00628	Range of Decimal Precision
6	250	RFR	O	[0..*]		00631	Reference (Normal) Range For Ordinal And Continuous Observations

OM2-2 Units of Measure (CE), required. Used only if the test contained in OM1 has numeric results. Contains the customary units of measure for the test.

OM2-3 Range of Decimal Precision (NM), required if known. Used only if the test contained in OM1 has numeric results. Specifies the total length in characters of the field needed to display the observation, and the number of digits displayed to the right of the decimal point. This is coded as a single number in the format <length>.<decimal-digits>. For example, a value of 6.2 implies 6 characters total (including the sign and decimal point) with 2 digits after the decimal point. For integer values, the period and <decimal-digits> portion may be omitted (that is, 5.0 and 5 are equivalent). More than one such mask may be transmitted (separated by repeat delimiters) when it is necessary to define possible multiple display formats.

OM2-6 Reference (Normal) Range for Ordinal and Continuous Observations, Optional. This field contains the reference (normal) ranges for "numeric" observations/tests with a nature code of A or C (see OM1-18 - Nature of Service/Test/Observation). The use of this field is discouraged (but not forbidden) by IHE. This field can identify different reference (normal) ranges for different categories of patients according to age, sex, race, and other patient conditions. Reference (normal) ranges however also depend on the Analyzer being used, a factor which isn't included in this field. Without having knowledge of the Analyzer generic statements about reference ranges may be clinically misleading and dangerous.

3.35.5.5 OM3 Categorical Service/Test/Observation Segment

The OM3 segment is used as part of the MFN^M09 message to convey information related to non-numeric tests, that is tests expecting a coded or free text result.

This segment description is taken from version 2.7 of the HL7® standard, since version 2.5 had a bug in the segment description.

Fields 2 to 6 are not constrained in length, as stated in the 2.7 HL7® standard.

Table 3.35.5.5-1: OM3 – Categorical Service/Test/Observation

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	4	NM	O	[0..1]		00586	Sequence Number - Test/Observation Master File
2		CWE	O	[0..1]		00636	Preferred Coding System
3		CWE	O	[0..*]		00637	Valid Coded Answers
4		CWE	O	[0..*]		00638	Normal Text/Codes for Categorical Observations
5		CWE	O	[0..*]		00639	Abnormal Text/Codes for Categorical Observations
6		CWE	O	[0..*]		00640	Critical Text/Codes for Categorical Observations
7	2..3	ID	O	[0..1]	0125	00570	Value Type

OM3-1 Sequence Number - Test/Observation Master File, optional.

HL7® 2.7 definition:

If used, this field contains the same value as the sequence number of the associated OM1 segment.

OM3-2 Preferred Coding System, optional.

This field is used in case there is one coding system, from which the valid values for the observations will be taken. Record the preferred coding system for this observation (e.g., ICD-10, SNOMED CT ...).

OM3-3 Valid Coded Answers, optional.

This field is used in case the list of coded answers is easily enumerated. It contains the list of valid coded answers. Multiple values in this field shall be separated with a repeat delimiter.

OM3-4 Normal Text/Codes for Categorical Observations, optional.

This field is used to specify the list of answers that are considered normal for that test.

The format of this field is:

- The first component is a code taken from a standard code source list.
- The second component is the text associated with the code (i.e., the meaning of the code).
- The third component is the identification of the coding system. When only a text description of a possible answer is available, it is recorded as ^<text>.

Multiple values in this field shall be separated with a repeat delimiter.

OM3-5 Abnormal Text/Codes for Categorical Observations, optional.

This field is used to specify the list of answers that are considered abnormal for that test.

Same structure as OM3-4.

OM3-6 Critical Text/Codes for Categorical Observations, optional.

This field is used to specify the list of answers that are considered critical for that test.

Same structure as OM3-4.

OM3-7 Value Type, optional.

If used, this field contains the allowed data type for a single categorical observation (code A in OM1-18 - Nature of Observation).

3.35.5.6 OM4 Segment: Observations that Require Specimens

The OM4 segment is used to convey information related to the (collection of) specimen required for the test/battery. This information can be used by Order Placers (e.g., at the ward) to collect the specimen.

Table 3.35.5.6-1: OM4 – Observations that Require Specimens

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
3	60	TX	R	[1..1]		00643	Container Description
4	20	NM	O	[0..1]		00644	Container Volume
6	250	CE	O	[0..1]		00646	Specimen
10	20	CQ	O	[0..1]		00650	Normal Collection Volume
11	20	CQ	O	[0..1]		00651	Minimal Collection Volume

OM4-3 Container Description (TX), required. Used only if OM1-4 contains "Y"; contains a textual description of the type of container used for collection of the sample, e.g., "Red capped tube #2".

OM4-4 Container Volume (NM), optional, indicates the capacity of the container

OM4-6 Specimen (CE), optional. See SPM-4 for additional information. The actor shall use one and the same vocabulary table for OM4-6 and SPM-4 if the Code Set Master is also an Order Filler Actor.

OM4-10 Normal Collection Volume (CQ), optional, contains the normal specimen volume required by the lab. This is the amount used by the normal methods and provides a sufficient amount to repeat the procedure at least once if needed. The default unit is milliliters (ml).

OM4-11 Minimal Collection Volume (CQ), optional, contains the volume needed by the most specimen sparing method (e.g., using micro techniques). The minimum amount allows for only one determination. The default unit is milliliters (ml).

3.35.5.7 OM5 – Observation Batteries

Table 3.35.5.7-1: OM5 – Observation Batteries

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
2	250	CE	R	[1..*]		00655	Test/Observations Included within an Ordered Test Battery

OM5-2 Test/Observations Included within an Ordered Test Battery, required, contains the codes and names of all tests/observations included within a single battery.

If the OM1 segment defined serum electrolytes, this field might look like the following: 84132^potassium^AS4~84295^sodium^AS4~82435^chloride^AS4~82374^HCO3^^AS4

3.35.5.8 MFA - Master File Acknowledgement Segment

The MFA – Master File Acknowledgment segment is defined in the following table.

Table 3.35.5.8-1: MFA – Master File Acknowledgment Segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	3	ID	R	[1..1]	0180	00664	Record-Level Event Code
2	20	ST	R	[1..1]		00665	MFN Control ID
3	26	TS	O	[0..1]		00668	Event Completion Date/Time
4	250	CE	R	[1..1]	0181	00669	MFN Record Level Error Return
5	250	CE	R	[1..1]		01308	Primary Key Value - MFA
6	3	ID	R	[1..1]	0355	01320	Primary Key Value Type - MFA

MFA-1 Record-Level Event Code (ID), required, shall contain the value MAD (add record to master file).

MFA-2 MFN Control ID (ST) is required and contains an identifier that uniquely identifies the change to the record.

MFA-4 MFN Record Level Error Return (CE), required, contains the status of the requested update. The actors of IHE Laboratory Technical Framework should support the following values:

Table 3.35.5.8-2: MFN record-level error return

Value	Description
S	Successful posting of the record defined by the MFE segment
U	Unsuccessful posting of the record defined by the MFE segment

MFA-5 Primary Key Value – MFA, required, uniquely identifies a record of the code set. It contains the same value as MFE-4.

MFA-6 Primary Key Value Type - MFA (ID), required, contains the value CE (coded element).

3.35.6 Expected Actions

The Code Set Consumer must replace its corresponding code set by the received code set. Codes which have been removed from the code set are not to be used by the receiving system any more from the effective date/time given in the message. Codes which have been removed should not be deleted but be flagged as disabled/invalid for backward compatibility reasons. New added codes are usable from the effective date/time given in the message.

3.35.7 Batch Message Static Definitions

3.35.7.1 Trigger Events

BHS

[MFN^M08] – the Code Set Master sends a full set of observation codes.

[MFN^M09] – the Code Set Master sends a full set of non-numeric observation codes.

[MFN^M10] – the Code Set Master sends a full set of battery codes.

[MFN^M11] – the Code Set Master sends a full set of calculated observation codes.

BTS

3.35.7.2 Message Semantics

The semantics combines those of the message static definitions of section 18.5.2

3.35.7.3 Batch Message

Table 3.35.7.3-1: Batch Message Static Definition

Segment	Meaning	Usage	Card	HL7
BHS	Batch Header Segment	R	[1..1]	2
{				
[	--- Start MFN^M08 message (Test/Observation Numeric)	O	[0..1]	8
MSH	Message Header	R	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	R	[1..*]	8
MFE	Master File Entry	R	[1..1]	8
OM1	General Segment	R	[1..1]	8
[OM2]	Numeric Observation Segment	O	[0..1]	8
[OM4]	Observations that Require Specimens	O	[0..1]	8
}	--- MASTER FILE ENTRY end			

Segment	Meaning	Usage	Card	HL7
]	--- End MFN^M08 message			
[	--- Start MFN^M09 message (Test/Observation Categorical)	O	[0..1]	8
MSH	Message Header	R	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	R	[1..*]	8
MFE	Master File Entry	R	[1..1]	8
OM1	General Segment	R	[1..1]	8
[	--- MF_TEST_CAT_DETAIL begin	O	[0..1]	8
OM3	Categorical Service/Test/Observation Segment	R	[1..1]	8
[{OM4}]	Observations that Require Specimens	O	[0..*]	8
]	--- MF_TEST_CAT_DETAIL end			
}	--- MASTER FILE ENTRY end			
]	--- End MFN^M09 message			
[	--- Start MFN^M10 message (Test/Observation Batteries)	O	[0..1]	8
MSH	Message Header	R	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	R	[1..*]	8
MFE	Master File Entry	R	[1..1]	8
OM1	General Segment	R	[1..1]	8
[	--- MF_TEST_BATT_DETAIL begin	RE	[0..1]	8
OM5	Observation Batteries	R	[0..1]	8
[{OM4}]	Observations that Require Specimens	O	[0..1]	8
]	--- MF_TEST_BATT_DETAIL end			
}	--- MASTER FILE ENTRY end			
]	--- End MFN^M10 message			
[	Start MFN^M11 message (Test/Observation Numeric)	O	[0..1]	8
MSH	Message Header	R	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	R	[1..*]	8
MFE	Master File Entry	R	[1..1]	8
OM1	General Segment	R	[1..1]	8
[				
OM6	Observation calculated from other observations		[0..1]	8
OM2	Numeric Observation Segment		[0..1]	8
]				

Segment	Meaning	Usage	Card	HL7
}	--- MASTER FILE ENTRY end			
]				
}				
BTS	Batch Trailer Segment	R	[1..1]	2

3.35.7.3.1 Batch Message Acknowledgement

1160 **Table 3.35.7.3.1-1: Batch Message Acknowledgment Static Definition**

Segment	Meaning	Usage	Card	HL7
BHS	Batch Header Segment	R	[1..1]	2
{				
[	--- Start MFK^M08 acknowledgment	O	[0..1]	2
MSH	Message Header	R	[1..1]	2
MSA	Acknowledgment	R	[1..1]	2
[{ERR}]	Error	C	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	R	[1..*]	8
MFA	Master File ACK segment	R	[1..1]	8
}	--- MASTER FILE ENTRY end			
]	--- End MFK^M08 message			
[	--- Start MFK^M09 acknowledgment	O	[0..1]	2
MSH	Message Header	R	[1..1]	2
MSA	Acknowledgment	R	[1..1]	2
[{ERR}]	Error	C	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	R	[1..*]	8
MFA	Master File ACK segment	R	[1..1]	8
}	--- MASTER FILE ENTRY end			
]	--- End MFK^M09 message			
[	--- Start MFK^M10 acknowledgment	O	[0..1]	2
MSH	Message Header	R	[1..1]	2
MSA	Acknowledgment	R	[1..1]	2
[{ERR}]	Error	C	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	R	[1..*]	8
MFA	Master File ACK segment	R	[1..1]	8
}	--- MASTER FILE ENTRY end			
]	--- End MFK^M10 message			

Segment	Meaning	Usage	Card	HL7
[	--- Start MFK^M11 acknowledgment	O	[0..1]	2
MSH	Message Header	R	[1..1]	2
MSA	Acknowledgment	R	[1..1]	2
[{ERR}]	Error	C	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	R	[1..*]	8
MFA	Master File ACK segment	R	[1..1]	8
}	--- MASTER FILE ENTRY end			
]	--- End MFK^M11 message			
}				
BTS	Batch Trailer Segment	R	[1..1]	2

3.35.7.4 BHS – Batch Header Segment

Table 3.35.7.4-1: Batch Header Segment Static Definition

SEQ	LEN	DT	USAGE	Card.	TBL#	ITEM#	Element name
1	1	ST	R	[1..1]		00081	Batch Field Separator
2	3	ST	R	[1..1]		00082	Batch Encoding Characters
3	227	HD	R	[1..1]		00083	Batch Sending Application
4	227	HD	R	[1..1]		00084	Batch Sending Facility
5	227	HD	R	[1..1]		00085	Batch Receiving Application
6	227	HD	R	[1..1]		00086	Batch Receiving Facility
7	26	TS	R	[1..1]		00087	Batch Creation Date/Time
8	40	ST	X	[0..0]		00088	Batch Security
9	20	ST				00089	Batch Name/ID/Type
10	80	ST				00090	Batch Comment
11	20	ST	RE	[0..1]		00091	Batch Control ID
12	20	ST	RE	[0..1]		00092	Reference Batch Control ID

BHS-1 Batch Field Separator, required: The IHE Laboratory Technical Framework requires that applications support HL7®-recommended value that is | (ASCII 124).

BHS-2 Batch Encoding Characters, required: This field contains the four characters in the following order: the component separator, repetition separator, escape character, and subcomponent separator. The IHE Laboratory Technical Framework requires that applications support HL7®-recommended values ^~\& (ASCII 94, 126, 92, and 38, respectively).

BHS-4 Batch Sending Facility (HD), required:

Components: <Namespace ID (IS)> ^ <Universal ID (ST)> ^ <Universal ID Type (ID)>

The IHE Laboratory Technical Framework requires that this field be populated with:

First component (required): Namespace ID. The name of the organizational entity responsible for the sending application.

Second component (optional): The URI (OID) of the organizational entity responsible for the sending application.

Third component (optional): The type of identification URI provided in the second component of this field. The codification of these three components is entirely site-defined. It may be detailed in the national extensions of this framework.

BHS-6 Batch Receiving Facility (HD), required:

Components: <Namespace ID (IS)> ^ <Universal ID (ST)> ^ <Universal ID Type (ID)>

The IHE Laboratory Technical Framework requires that this field be populated with:

First component (required): Namespace ID. The name of the organizational entity responsible for the receiving application.

Second component (optional): The URI (e.g., OID) of the organizational entity responsible for the receiving application.

Third component (optional): The type of identification URI provided in the second component of this field. The codification of these three components is entirely site-defined. It may be detailed in the national extensions of this framework.

BHS-11 Batch Control Id (ST), required in the initiating message: This field is used to uniquely identify a particular batch. It must be echoed back in BHS-12 – reference batch control ID of the responding batch of HL-7 MFK messages. The combination of this identifier and the name of the batch sending application (BHS-3) should be unique across the Healthcare enterprise.

BHS-12 Reference Batch Control (ID), required in the responding message: This field contains the value of the Batch Control Id (BHS-11) of the initiating batch of HL-7 MFN messages.

3.35.7.5 BTS – Batch Trailer Segment

Table 3.35.7.5-1: Batch Trailer Segment Static Definition

SEQ	LEN	DT	USAGE	Card.	TBL#	ITEM#	Element name
1	10	ST	O	[0..1]		00093	Batch Message Count
2	80	ST	O	[0..1]		00090	Batch Comment
3	100	NM	O	[0..*]		00095	Batch Totals

3.35.7.6 MFK Segment

Applications that receive HL7® messages defined in the IHE Laboratory Technical Framework shall send acknowledgements using the HL7® original acknowledgement mode. The Master File Application Acknowledgment message is defined in HL7® 2.5 Chapter 8. The structure of the acknowledgement messages is the same for all acknowledgements:

Table 3.35.7.6-1: MFK^M08, MFK^M09, MFK^M10, MFK^M11 Static Definition

Segment	Meaning	Usage	Card.	HL7
MSH	Message Header	R	[1..1]	2
MSA	Acknowledgment	R	[1..1]	2
[{ERR}]	Error	C	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	C	[0..*]	8
MFA	Master File ACK Segment	R	[1..1]	8
}	--- MASTER FILE ENTRY end			

The construction of MSH, MSA and ERR segments is defined in section 3.1 of the IHE Laboratory Technical Framework, Volume II. The ERR segment shall be used in case of negative acknowledgement, i.e., when the receiving application sends an error on one Master File entry.

The MASTER FILE ENTRY segment group is conditional upon the presence of errors (see the description of field MFI-6). The segment group shall only be populated with MFA Segment for those master file entries that could NOT be accepted. If the entire batch can be accepted by the receiver then the acknowledgement message shall not contain any MFA segments.

3.35.8 Expected Actions

The Code Set Consumer must replace its corresponding code set by the received code set. Codes which have been removed from the code set are not to be used by the receiving system any more from the effective date/time given in the message. Codes which have been removed should not be deleted but be flagged as disabled/invalid for backward compatibility reasons. New added codes are usable from the effective date/time given in the message.

4 Real World Use Cases

4.1 Guidelines

Each of the real world use cases in this section are to be considered as a template for handling a category of laboratory testing throughout all the transactions of the Laboratory Technical Framework. Only the major steps and interactions are described.

Each use case is described by a storyboard that describes the complete workflow in chronological order, completed by an interaction diagram, and illustrated by the most significant messages of this workflow.

The message descriptions are abbreviated, to focus on the main points of interest.

For brevity, only some of the application acknowledgements are shown.

The actors' names are abbreviated with their initials (OP, OF, AM, ORT). These abbreviations are also used in the MSH-3 (sending application) and MSH-5 (receiving application) fields.

All use cases assume that the placer order is related to a placer group number (ORC-4).

All tests are identified in OBX segments by their LOINC code when available.

Colors point out key information in the messages.

4.2 First Example for Barcode Labeling (LBL)

4.2.1 Storyboard

1. Dr. Yamada examines the patient (ID: 1111222) and orders liver function tests and blood count through the HIS terminal.
2. The patient goes to the blood collecting room.
3. The receptionist for blood collecting checks the test orders and accepts the reception through the HIS terminal.
4. The HIS sends the label information to the barcode labeling robotic system.
5. The robotic system issues the containers with barcode label.
6. The blood collector takes blood of the patient.

Human actors and organizations participating to the process:

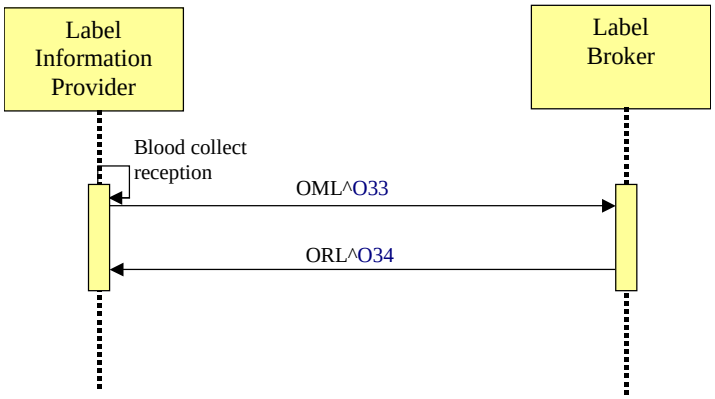
Assigning authority:	Suzuki national hospital
Placer:	Enter-gastric department
Label Broker:	LBL system
Ordering facility:	Enter-gastric department
Patient:	Taro Toyota, Patient hospital identifier: 1111222, Patient visit number: 3333444, class = outpatient

Orderer: Dr. Yamada. ID number 14789

ID numbers used by the workflow:

ID number	Value	Assigned by
Patient hospital ID	1111222	Admission office (ADT)
Patient visit number	3333444	Admission office (ADT)
Observation Order Code: liver function test	1234561	Enter-gastric department (OP)
Observation Order Code: Blood count	1234562	Enter-gastric department (OP)

4.2.2 Interaction Diagram



4.2.3 Messages

LAB-61(LIP→LB): New Label Delivery Request transmitted to the LB

```
MSH|^~\&|LIP|Enter-gastric department|LB|LBL system
|200701121348||OML^O33^OML_O33|001|P|2.5|||||USA||EN
PID|1||1111222^^^Suzuki National Hospital^PI||Toyota^Taro^^^^^L|19810101|M
PV1|1|O|||||||||||||||||3333444
SPM|1|1234560001||001^Venous blood|||||||P||||||20070112|||||||||1|021^Chemistry
ORC|NW|1234561|||||||200701121348|14789^Yamada^Jiro||14789^Yamada^Jiro|||||051^Enter-
gastric department
TQ1|||||||||R
OBR||1234561||17432^liver function^local|||||6.0|||||||14789^Yamada^Jiro
SPM|1|1234560002||001^Venous blood|||||||P||||||20070112|||||||||1|015^hematology
ORC|NW|1234562|||||||200701121348|14789^Yamada^Jiro||14789^Yamada^Jiro|||||051^Enter-
gastric department
TQ1|||||||||R
OBR||1234562||18655^blood count^local|||||2.0|||||||14789^Yamada^Jiro
```

The related acknowledgement message isn't shown.

4.3 Second Example for Barcode Labeling (LBL)

4.3.1 Storyboard

1. Dr. Yamada examines the patient (ID: 1111222) and orders liver function tests and blood count through the HIS terminal.
2. The patient goes to the blood collecting room.
3. The patient inserts his ID card to the reception machine for blood collecting.
4. The barcode labeling robotic system sends the query for label delivery to the HIS
5. The HIS sends the label information back to the barcode labeling robotic system.
6. The robotic system issues the containers with barcode label.
7. The blood collector takes blood of the patient.

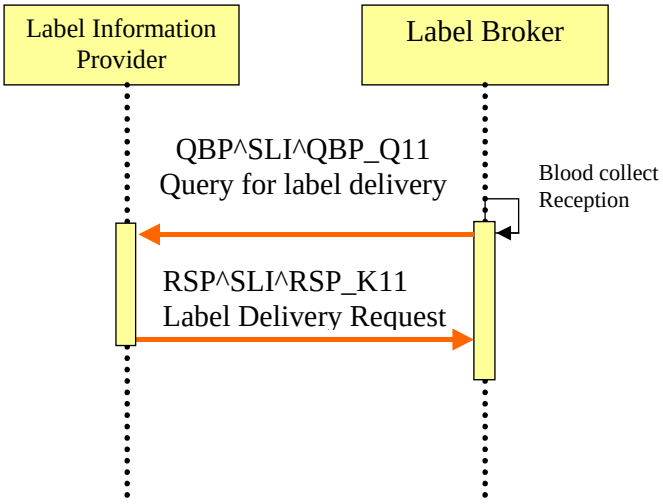
Human actors and organizations participating to the process:

Assigning authority:	Suzuki national hospital
Placer:	Enter-gastric department
Label Broker:	LBL system
Ordering facility:	Enter-gastric department
Patient:	Taro Toyota, Patient hospital identifier: 1111222, Patient visit number: 3333444, class = outpatient
Orderer:	Dr. Yamada. ID number 14789

ID numbers used by the workflow:

ID number	Value	Assigned by
Patient hospital ID	1111222	Admission office (ADT)
Patient visit number	3333444	Admission office (ADT)
Observation Order Code（liver function test）	1234561	Enter-gastric department (OP)
Observation Order Code（Blood count）	1234562	Enter-gastric department (OP)

4.3.2 Interaction Diagram



4.3.3 Messages

LAB-62 (LB→LIP): Query for label delivery

```
MSH|^~\&|LB|LBL system |LIP|Enter-gastric department |200701121348||
QBP^SLI^QBP_Q11|001|P|2.5|||||USA||EN
QPD|SLI^Specimen Labeling Instructions^IHE_LABTF|0001|1111222
RCP|I||R
```

LAB-62 (LIP→LB): Label Delivery Request transmitted to the LB

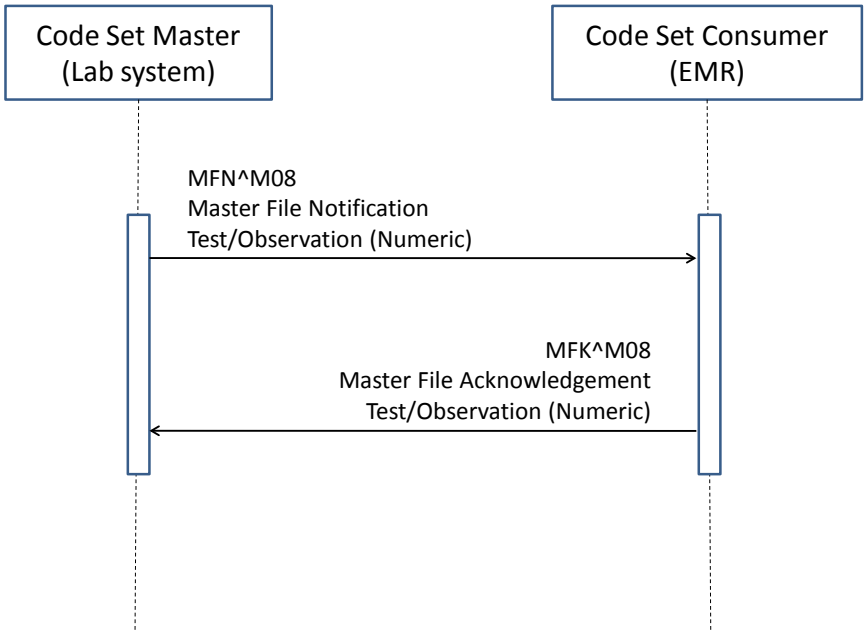
```
MSH|^~\&|LIP|Enter-gastric department|LB|LBL system |200701121348||
RSP^SLI^RSP_K11|001|P|2.5|||||USA||EN
PID|1||1111222^^^Suzuki National Hospital^PI||Toyota^Taro^^^^^L|19810101|M
PV1|1|O|||||||||||||||||3333444
SPM|1|1234560001||001^Venous blood|||||||P||||||20070112|||||||||1|021^Chemistry
ORC|NW|1234561|||||||200701121348|14789^Yamada^Jiro||14789^Yamada^Jiro|||||051^Enter-
gastric department
TQ1|||||||||R
OBR||1234561||17432^liver function^local|||||6.0|||||||14789^Yamada^Jiro
SPM|1|1234560002||001^Venous blood|||||||P||||||20070112|||||||||1|015^hematology
ORC|NW|1234562|||||||200701121348|14789^Yamada^Jiro||14789^Yamada^Jiro|||||051^Enter-
gastric department
TQ1|||||||||R
OBR||1234562||18655^blood count^local|||||2.0|||||||14789^Yamada^Jiro
```

4.4 First Example Laboratory Code Set Management: Numeric Observations

4.4.1 Storyboard

This example reflects a use case in which a laboratory information system is broadcasting its catalog of tests, without the batch option. The interaction below carries the numeric tests.

4.4.2 Interaction Diagram



4.4.3 Messages

The message below is a Dutch (NLD) language example containing a master file definition for numeric tests. The master file has the version ID "1.2". The (optional) OM4 segment defines the type of container (e.g., "*stolbuis rode dop4*" = red capped blood tube #4) and specimen type (e.g., "BLDV^*volbloed*" = venous blood) which is associated with a test. This information is used by the OP in those cases where the OP is responsible for collecting the sample.

```
MSH|^~\&|OF|LabSystem|OP||20050205094510||MFN^M08^MFN_M08|2106|T|2.5|||||NLD|8859/1|NL
|
MFI|OMA|OF_OMA_NL_1.2|REP|||ER|
MFE|MAD|1846||1846^CREABL/Creatinine^L|CE|
OM1|1|1846^CREABL/Creatinine^L|NM|Y|K231^Klinisch Chemisch
Laboratorium^L|||Creatinine|||||||||A|
OM2|1|umol/l|6.0||
OM4|1||stolbuis rode dop4||ml|BLDV^volbloed^HL70487|
MFE|MAD|1848||1848^CREAUV/Creatinine^L|CE|
OM1|2|1848^CREAUV/Creatinine^L|NM|Y|K231^Klinisch Chemisch
Laboratorium^L|||Creatinine|||||||||A|
OM2|2|mmol/l|6.0||
OM4|2||24-uurs bokaal|||UR^urine^HL70487|
MFE|….  (other master file entries not shown)
```


Response message:

Note that those additions that are successful are not explicitly acknowledged. Each OM1 segments that is problematic to the receiver causes a MFA segment to be present in the acknowledgement message. In this example, all updates are accepted except for 1848.

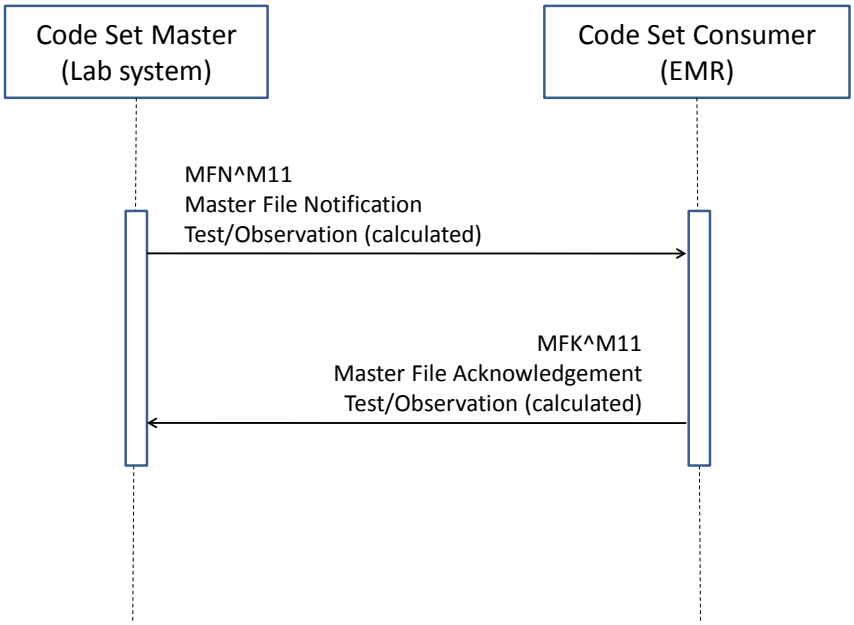
```
MSH|^~\&|OP||OF|LabSystem|20050205094520||MFK^M08^MFK_M01|234443|T|2.5|||||NLD|8859/1|
NL|
MSA|AA|2106|
MFI|OMA|OF_OMA_NL_1.2|REP|||ER|
MFA|MAD|1848||U^Duplicate ID|1848^CREAUV/Creatinine^L|CE
```

4.5 Second Example of Laboratory Code Set Management: Calculated Observations

4.5.1 Storyboard

This example reflects a use case in which a laboratory information system is broadcasting its catalog of tests, without the batch option. The interaction below carries the calculated tests.

4.5.2 Interaction Diagram



4.5.3 Messages

The message below is a Dutch (NLD) language example containing a master file definition for calculated numeric tests. The calculation algorithm is shown (in textual form) in the OM6 segment.

```
MSH|^~\&|OF|LabSystem|OP||20050205094520||MFN^M11^MFN_M11|2107|T|2.5|||||NLD|8859/1|NL
|
MFI|OMD|OF_OMD_NL_1.1|REP|||ER|
MFE|MAD|1849||1849^CLEA/Creatinine clearance^L|CE
OM1|1|1849^CLEA/Creatinine clearance^L|NM|Y|K231^Klinisch Chemisch
Laboratorium^L|||Creatinine clearance|||||||||C|
OM6|1|(CREAUV * HOEV) / (CREASE * 1440)
OM2|1|ml/min|4.0||
MFE|…. (other master file entries not shown)
```

Response message:

The entire contents of the message are accepted.

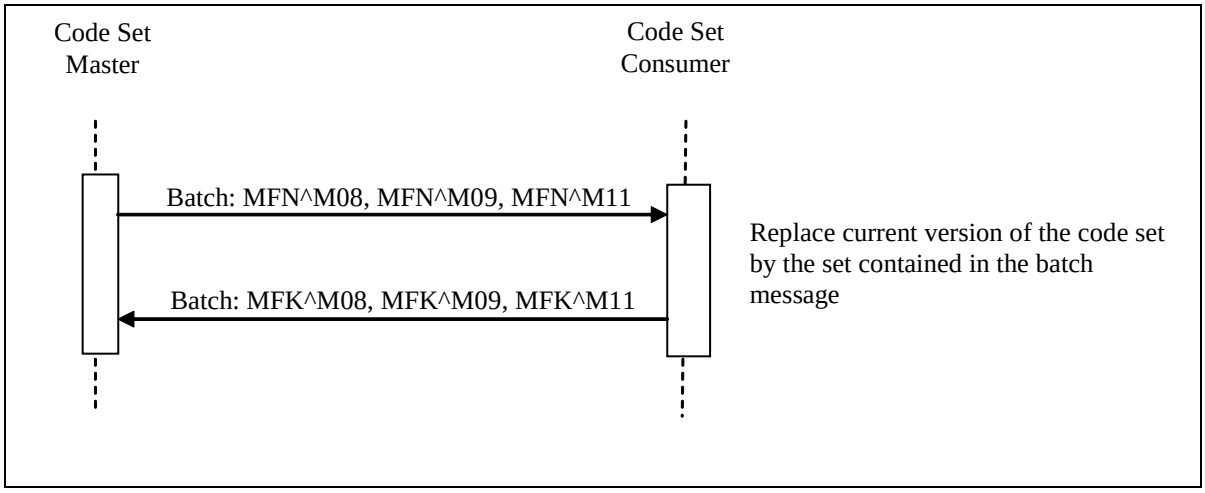
```
MSH|^~\&|OP||OF|LabSystem|20050205094530||MFK^M11^MFK_M01|234450|T|2.5|||||NLD|8859/1|
NL|
MSA|AA|2107|
MFI|OMD|OF_OMD_NL_1.1|REP|||ER|
```

4.6 Third Example of Laboratory Code Set Management: Batch Option

4.6.1 Storyboard

This example reflects a use case in which a laboratory information system is broadcasting its catalog of tests, with the batch option. A single batch carries the messages of numeric observations, categorical observations and calculated observations

4.6.2 Interaction Diagram



4.6.3 Messages

The receiver shall drop all existing records and register the new code set version from the received batch.

```
BHS|^~\&|Lims|Sending Facility|Receiver|Receiving Facility|20090422165845||||4329431|
MSH|^~\&|Lims|Sending Facility|Receiver|Receiving
Facility|20090422165845||MFN^M08^MFN_M08|M08_215|D|2.5|||||FR|8859/1|FRA
MFI|OMA|Lims_OMA_FRA|REP||20090422165845|ER
MFE|MAD|215_335088||335088^Creatinine^L|CE
OM1|1|14682-9^Creatinine^LOINC|NM|Y|B^B^L|||B_CREA|||||||||A|00100060^Creatinine
clearance^L|001000600040
OM2|1|µmol/l^µmol/l^ISO|20.0|||27&53^^&730.5^^^^~27&62^^730.5&1826.25^^^^~27&71^^1826.
25&2922.0^^^^~35&71^^2922.0&4383.0^^^^~35&80^^4383.0&5113.5^^^^~44&88^Male^&5844.0^^^^
~53&97^Male^5844.0&7305.0^^^^~44&88^Female^&18262.5^^^^~53&106^Male^7305.0&20088.75^^^
^~44&97^Female^18262.5&43830.0^^^^~53&115^Male^20088.75&43830.0^^^^
OM4|||purple-top glass tube|||P5HEPG^P5HEPG^L
MFE|MAD|215_335851||335851^Bicarbonates^L|CE
OM1|4|12466-
2^Bicarbonates^LOINC|NM|Y|B^B^L|||B_CO2|||||||||A|0010^Chemistry^L|00100055
OM2|4|mmol/l^mmol/l^ISO|20.0|||23&28^^^^^^
OM4|||purple-top glass tube|||P5HEPG^P5HEPG^L
MFE|MAD|215_336040||336040^Sodium^L|CE
OM1|8|2951-2^Sodium^LOINC|NM|Y|B^B^L|||B_NA|||||||||A|0010^Chemistry^L|00100010
OM2|8|mmol/l^mmol/l^ISO|20.0|||135&145^^^^^^
OM4|||purple-top glass tube|||P5HEPG^P5HEPG^L
MFE|MAD|215_336046||336046^Potassium^L|CE
OM1|9|12372-1^Potassium^LOINC|NM|Y|B^B^L|||B_K|||||||||A|0010^Chemistry^L|00100015
OM2|9|mmol/l^mmol/l^ISO|20.1|||3.5&5^^^^^^
OM4|||purple-top glass tube|||P5HEPG^P5HEPG^L
MFE|MAD|215_336067||336067^Chloride^L|CE
OM1|10|26254-3^Chloride^LOINC|NM|Y|B^B^L|||B_CL|||||||||A|0010^Chemistry^L|00100017
OM2|10|mmol/l^mmol/l^ISO|20.0|||95&105^^^^^^
OM4|||purple-top glass tube|||P5HEPG^P5HEPG^L
MFE|MAD|215_336178||336178^Ureum^L|CE
OM1|12|32664-7^Ureum^LOINC|NM|Y|B^B^L|||B_UREE|||||||||A
OM2|12|mmol/l^mmol/l^ISO|20.0|||2&9^^^^^^
OM4|||purple-top glass tube|||P5HEPG^P5HEPG^L
```



```
MSH|^~\&|Lims|Sending Facility|Receiver|Receiving
Facility|20090422165850||MFN^M09^MFN_M09|M09_215|D|2.5|||||FR|8859/1|FRA
MFI|OMB|Lims_OMB_FRA|REP||20090422165850|ER
MFE|MAD|215_334365||334365^Freezing method^L|CE
OM1|1|Z00010-1^Freezing
method^LOINC|CE|Y|H^H^L|||HF_METHODE||||||||||A|0020^Other^L|00200010
OM3|1|L||Various^Various freezing method^L~Ficoll^Ficoll freezing method^L~Light^Light
freezing method^L
OM4|||Red-top edta tube|||H_SG^H_SG^L
MSH|^~\&|Lims|Sending Facility|Receiver|Receiving
Facility|20090422165851||MFN^M10^MFN_M10|M10_215|D|2.5|||||FR|8859/1|FRA
MFI|OMC|Lims_OMC_FRA|REP||20090422165851|ER
MFE|MAD|215_585128||585128^Electrolytes^L|CE
OM1|4|Z0003-1^Electrolytes^LOINC||Y|B^B^L|||Electrolytes|||||||||P
OM5|4|2951-2^^LOINC~12372-1^^LOINC~12466-2^^LOINC~26254-3^^LOINC
OM4|||purple-top glass tube|||P5HEPG^P5HEPG^L
MFE|MAD|215_585135||585135^Kidney tests^L|CE
OM1|5|Z0004-1^Kidney tests^LOINC||Y|B^B^L|||Kidney tests|||||||||P
OM5|5|32664-7^^LOINC~14682-9^^LOINC
OM4|||purple-top glass tube|||P5HEPG^P5HEPG^L
MSH|^~\&|Lims|Sending Facility|Receiver|Receiving
Facility|20090422165853||MFN^M11^MFN_M11|M11_215|D|2.5|||||FR|8859/1|FRA
MFI|OMD|Lims_OMD_FRA|REP||20090422165853|ER
MFE|MAD|215_339307||339307^Calculated LDL^L|CE
OM1|1|22748-2^Calculated
LDL^LOINC|NM|N|B^B^L|||B_LDL||||||||||C|0010^Chemistry^L|00100050
OM2|1|g/l^g/l^ISO|20.2
MFE|MAD|215_353143||353143^Calculated Clearance^L|CE
OM1|2|Z010-3^Calculated Clearance^LOINC|NM|N|B^B^L|||B_U_SAU|||||||||C
OM2|2|ml/s^ml/s^ISO|20
BTS|4|
```

Response message:

The entire contents of the message are accepted.

```
[insert response here]
```

